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Original Submission

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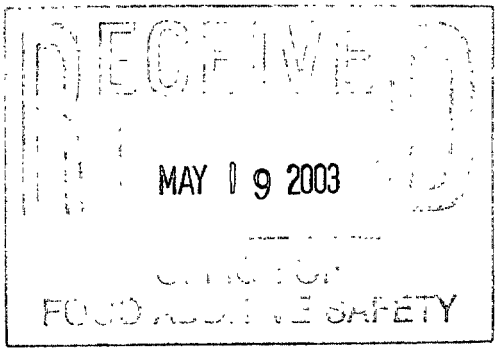
[redacted]

ROBERT H. SINDT
ATTORNEY AT LAW

1850 M Street, N.W., Suite 400
Washington, D.C. 20036
Phone 202-466-4500 • Fax 202-466-5777 • E-mail rsindt@krooth.com

May 15, 2003



Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration
HFS-200
5100 Paint Branch Parkway
College Park, MD 20740-3835

Re: GRAS Notice—*Propionibacterium freudenreichii* subsp. *shermanii* cultured microbial growth inhibitor (MicroGARD®)

Dear Sir or Madame:

On behalf of my client, Rhodia Inc., please accept the attached documentation, in compliance with the GRAS notification procedure set out in the April 17, 1997 Federal Register (62 FR 18937), as submission of notice of a GRAS exemption claim for the above referenced substance, i.e. specified food uses of *Propionibacterium freudenreichii* subsp. *shermanii* cultured microbial growth inhibitor (MicroGARD®). As specified in the aforementioned proposed rule, this GRAS notice is submitted in triplicate with each containing: a signed exemption claim; detailed information on the substance, on any self-limiting levels of use, and on the basis for the determination; and an appendix containing further referenced and substantiating information on the substance.

Please promptly contact me should you have any question regarding the submitted notice. I look forward to receiving acknowledgment of receipt of this notice and to a timely response regarding the noticed substance. Thank you.

Sincerely,

Robert H. Sindt

Enc.

Cc : Kevin O. Gillies, Rhodia Inc.

RHS/bs

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GENERALLY RECOGNIZED AS SAFE NOTICE

Propionibacterium freudenreichii subsp. *shermanii* cultured microbial growth inhibitor (MicroGARD)

MAY 2003

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[redacted]

ROBERT H. SINDT
ATTORNEY AT LAW

1850 M Street, N.W., Suite 400
Washington, D.C. 20036
Phone 202-466-4500 • Fax 202-466-5777 • E-mail

May 15, 2003

Dr. Linda Kahl
Office of Premarket Approval (HFS-200)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, SW
Washington, DC 20204

Re: GRAS Notice-Exemption Claim for *Propionibacterium freudenreichii* subsp. *shermanii* cultured microbial growth inhibitor (MicroGARD®)

Dear Dr. Kahl:

On behalf of my client, Rhodia Inc., and in accordance with FDA's proposed rule of April 17, 1997 (62 FR 18938) relating to the filing of generally recognized as safe (GRAS) notices, please accept this claim and the attached information, submitted in triplicate, for that purpose as it relates to the use of *Propionibacterium freudenreichii* subsp. *shermanii* cultured microbial growth inhibitor (hereafter termed MicroGARD®) in certain foods. Specifically, Rhodia claims that use of MicroGARD® as an antimicrobial agent in certain cheeses, sauces, salad dressings, sausages, soups, deli salads, salsas, pasta, tortillas, muffins, cereal bars, sour cream, yogurt and hash brown potatoes (as specified in the detailed information submitted herewith) is exempt from the premarket approval requirements of the Federal Food, Drug and Cosmetic Act based on its determination that such use is GRAS. In conformity with the requirements outlined in the proposed rule, the following information is included with this exemption claim:

(i) Name and Address of the Notifier: Rhodia Inc.
CN 7500
259 Prospect Plains Road
Cranbury, NJ 08512-7500

(ii) Common or Usual Name of Notified Substance: *Propionibacterium freudenreichii* subsp. *shermanii* cultured microbial growth inhibitor

(iii) Applicable Conditions of Use: MicroGARD® is manufactured in compliance with current Good Manufacturing Practice as specified in 21 CFR Part 110 and the Food Chemicals Codex, Fourth Edition and any subsequent amendment thereto. MicroGARD® is the product of safe and suitable *Propionibacterium*

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freudenreichii subsp. *shermanii* culture fermentation in skim milk or dextrose that is standardized with skim milk solids or maltodextrin, respectively. It is used as an antimicrobial agent in the above specified foods at levels not to exceed current good manufacturing practice in accordance with 21 CFR 184.1(b). Current good maunfacturing practice results in a maximum use level of MicroGARD® of up to 2% (%w/w) in finished products. All population age groups are expected to consume the substance.

(iv) Basis for the GRAS Determination: Scientific procedures as supported by a recent history of experience based on common use in food.

(v) Availability to FDA of Data and Information that are Basis of Determination: The data and information forming the basis for Rhodia's GRAS determination and the exemption claim asserted herein are available for FDA review and copying during reasonable business hours at the following address, or will be sent to FDA upon request: Robert H. Sindt, Attorney at Law
Suite 400
1850 M Street, NW
Washington, DC 20036
Phone: (202) 466-4500

Consequently, on the basis of the above specified information, and the additional requested information as specified in the proposed rule and submitted with this letter, please accept this as Rhodia's claim of exemption from the statutory premarket approval requirements for the use of *Propionibacterium freudenreichii* subsp. *shermanii* cultured microbial growth inhibitor (MicroGARD®), as an antimicrobial agent in certain cheeses, sauces, salad dressings sausages, soups, deli salads, salsas, pasta, tortillas, muffins, cereal bars, sour cream, yogurt and hash brown potatoes. Should you have any questions regarding the submission of this notice, please contact me at the above number. Thank you for your prompt consideration of, and response to, this notice.

Sincerely,

Robert H. Sindt

RHS:bs

Attachments

000023-002

MICROGARD®-GRAS NOTICE INFORMATION

(2) DETAILED INFORMATION ABOUT THE IDENTITY OF THE NOTIFIED SUBSTANCE (§170.36(c)(2))

- Common and Usual Name of the Food Grade Substance: *Propionibacterium freudenreichii* subsp. *shermanii* cultured microbial growth inhibitor (hereinafter termed "MicroGARD®")

- Chemical Name for MicroGARD®: None

- Chemical Abstract Service (CAS) Registry Number for MicroGARD®: 129038-82-0

- Empirical Formula for MicroGARD®: None

- Structural Formula for MicroGARD®: None

- Quantitative Composition for MicroGARD®: MicroGARD® is a commercially available food ingredient that is produced by culture fermentation utilizing *Propionibacterium freudenreichii* subsp. *shermanii* in GRAS substances, either skim milk or dextrose. MicroGARD® is a liquid or dry fermentate that is standardized with GRAS food substances. Both dairy MicroGARD® and nondairy MicroGARD® products are produced to provide flexibility in addressing dairy product allergy concerns and customer formulation preferences in end product uses. Dairy

MicroGARD® (cultured skim milk) is standardized with skim milk solids, while nondairy MicroGARD® (cultured dextrose) is standardized with maltodextrin.

- Method of Manufacture for MicroGARD®: MicroGARD® is manufactured in compliance with current Good Manufacturing Practice specified in 21 CFR, part 110, and in the Food Chemicals Codex, Fourth Edition and any subsequent amendment thereof.

  MicroGARD® is manufactured at USDA inspected dairy plants certified to process Grade A milk, in accordance with Food and Drug Administration and Interstate Milk Shippers standards. All methods of analyses utilized comply with Standard Methods for the Examination of Dairy Products of the American Public Health Association.

  The source organism used in the culture fermentation to manufacture MicroGARD®, *Propionibacterium freudenreichii* subsp. *shermanii* (ATCC strain 9616), is a non-pathogenic, non-toxigenic organism that has a long history of safe use in food. The culture is maintained as frozen 1 ml. vials at 80°C, and the identity of the ATCC strain 9616 to be *Propionibacterium freudenreichii* ssp. *shermanii* is independently verified. Each seed lot in the culture bank is fully characterized to insure the identity of the seed strains. Concentrated starter for the industrial fermentation is produced from the seed vials. To ensure purity of the inoculum, the medium used for starter production is sterilized, and all starter batches are thoroughly analyzed for possible contaminants prior to use.

  In actual production, MicroGARD® is manufactured through a specific time and temperature controlled fermentation of skim milk or dextrose with the

Propionibacterium freudenreichii subsp. *shermanii* organism. Skim milk or dextrose may be supplemented with small amounts of yeast extract and sodium acetate as incidental additives. The mixture is sterilized and cooled to the incubation temperature. The pH is then lowered to minimize the outgrowth of contaminants. The mixture is then inoculated with frozen, concentrated cultures and allowed to incubate for a time sufficient to reach the fermentation endpoint.

After the required incubation period, the pH is neutralized, followed by standardization with safe and suitable GRAS solids, either Grade A skim milk or maltodextrin. The mixture is pasteurized, condensed, repasteurized and dried. MicroGARD® is then packaged and stored in a cool, dry environment. A liquid form of MicroGARD® is also produced, eliminating the drying stage. It is noted that after manufacture, all MicroGARD® is tested for microbiological integrity by the manufacturer and by an independent certified laboratory. Again, the final product testing methods comply with standard Methods for the Examination of Dairy Products of the American Public Health Association.

- Characteristic Properties of MicroGARD®: MicroGARD® is produced by fermentation utilizing *Propionibacterium freudenreichii* subsp. *shermanii* (ATCC strain 9616), a safe and suitable bacterium, in either skim milk or dextrose that is standardized with skim milk solids or with maltodextrin. In powdered form, MicroGARD® has an off-white color, a slight cooked odor, and a buttermilk flavor. MicroGARD® has been demonstrated in a variety of foods to inhibit spoilage

microbial outgrowth, specifically Gram negative psychrotrophs and select yeast and molds.

- Content of Potential Human Toxicants for MicroGARD®: None

- Specifications for Food Grade MicroGARD®: MicroGARD® is a product produced by culture fermentation utilizing *Propionibacterium freudenreichii* subsp. *shermanii* (ATCC strain 9616) in skim milk or dextrose that is standardized with skim milk solids or maltodextrin. MicroGARD® typically has a pH of 7.0-7.3, with dairy MicroGARD® (cultured skim milk) having a moisture content of 2.9% and non-dairy MicroGARD® (cultured dextrose) having a moisture content of 2.1%. Typical MicroGARD® microbiological analysis follows:

Standard Plate Count	Less than 2,500
Yeast & Mold	Less than 10
Lactobacillus	Less than 10
Coliforms	Negative
E. coli	Negative
Salmonella	Negative
Staphylococcus (C.P.)	Negative

MICROGARD®-GRAS NOTICE INFORMATION

(3) INFORMATION ON SELF-LIMITING LEVELS OF USE, IF ANY (§170.36(c)(3))

- No information on self limiting levels of MicroGARD® use is noted.

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MICROGARD®-GRAS NOTICE INFORMATION

(4) DETAILED SUMMARY OF THE BASIS FOR GRAS DETERMINATION (§170.36(c)(4))

Rhodia's determination, that the notified uses of MicroGARD® (as an antimicrobial agent in certain cheeses, sauces, salad dressings, sausages, soups, deli salads, salsas, pasta, tortillas, muffins, cereal bars, sour cream, yogurt, and hash brown potatoes) are exempt from premarket approval requirements because such uses are GRAS, is based on scientific procedures as supported by a recent history (nearly 20 years) of experience based on common use in food. The determination has been confirmed by independent panels of scientific experts convened by Rhodia to conduct such critical reviews. Each member of the independent expert panels were qualified by their scientific training and experience to evaluate the safety of substances used in food. The independent expert panels' reports and determinations, dated March 1966 and October 2000, are included in their entirety in the Appendix attached hereto.

(A) Safety of MicroGARD®:

MicroGARD® is produced by fermentation utilizing *Propionibacterium freudenreichii* subsp. *shermanii* (ATCC strain 9616), a safe and suitable bacterium, in a GRAS substance, either skim milk or dextrose, that is standardized with a GRAS substance, either skim milk solids or maltodextrin. The culturing organism is safe and suitable for use in foods, having been identified as the organism producing characteristic qualities in Swiss and

emmentaler cheeses through the ages, and as recognized by FDA in its standards of identity for such cheeses at 21 CFR 133.195 (see Appendix).

(1) Safety and Suitability of Culturing Organism. The propionibacteria are gram-positive, aerotolerant rods which are commonly divided taxonomically in two categories, (1) classical or dairy type and (2) coryneform type. The classical or dairy type used in MicroGARD® is normally isolated from raw milk or dairy products and has been divided taxonomically into the following four species:

- *P. freudenreichii*
- *P. jensenii*
- *P. thoenii*
- *P. acidipropionici*

Propionibacterium freudenreichii is a well-characterized, non-pathogenic, non-toxigenic, homogeneous species grouping which differs from other members of the classical propionibacteria in that strains:

- exhibit very short rod morphology, often nearly coccal in shape;
- are thermo-tolerant;
- ferment a restricted range of carbohydrates;
- contain meso-DAP peptidoglycan instead of the L-isomer as cell wall constituents; and
- are non-hemolytic.

(Cummins and Johnson, 1986).

Recent evaluation of the species groupings noted above by numerical analysis (Britz and Reidel 1995) confirmed the major species as documented among the classical propionibacteria. Specifically, the "*freudenreichii*" major group, was found to be made up of 7 sub-clusters. PCR/RFLP (polymerase chain reaction / restriction fragment length polymorphism) profiles were similar for all the strains in this group. In the past, the species *freudenreichii* has been subdivided into subspecies *freudenreichii* and *shermanii* on the basis of nitrate reduction and lactose fermentation, but the subspecies could not be positively separated by the numerical analysis.

Man has relied on fermentation for centuries as an effective and economical way to preserve foods, including milk. Fermented milks and cheeses were standard foods in early Egyptian and Greek diets, and Roman conquests are thought to be responsible for spreading fermentation techniques into northern Europe. Swiss and emmentaler cheesemaking in what is now Switzerland has been traced back to approximately 58 B.C (Kosikowski, 1982).

For centuries, man relied upon the growth of indigenous microorganisms from the environment or the addition of portions of previously fermented milk to produce the desired milk fermentation product. Beginning in the later part of the 19th and early years of the 20th century, microbiologist began to isolate and identify the microorganisms responsible for the transformation of milk to edible fermented milk products.

In 1906 Edouard von Freudenreich, a Swiss microbiologist, first isolated this species, which was named in his honor, *Propionibacterium freudenreichii.*

Demonstration that propionibacteria were essential for flavor development in Swiss cheese was accomplished in 1926 (Cummins and Johnson, 1986; Kosikowski, 1982; Langsrud and Reinbold, 1973).

The genus *freudenreichii*, sometimes further differentiated into subspecies *freudenreichii* or *shermanii* (see above) , has been in commerce as a pure strain starter culture and used in milk fermentations since the 1950s in both the U. S. and Europe (Morgensen, *et. al.*, 2002). Although not all appropriate uses of *Propionibacteria* species are specified in FDA regulations and directives, the use of propionic acid-producing bacterial cultures are specifically recognized in the manufacture of Swiss and emmentaler cheese as provided for in 21 CFR 133.195. The propionibacteria are undergoing broader study and use outside dairy products and such uses provide further scientific evidence for the general recognition of safety of the organisms. Specifically, classical *Propionibacterium* species including *P. freudenreichii* have undergone trials as human and animal probiotics including trials in elderly hospital patients and children with intestinal disorders. The probiotic activity of these organisms has been clearly demonstrated in animal studies and appears to be associated with formation of propionic acid, as well as other minor acid components, bacteriocins, vitamin B_{12}, better exploitation of fodder and ability to act as a growth stimulator for other beneficial bacteria in the intestines. Human feeding trials appear to indicate the positive effects of ingesting propionibacteria. It is important to note that in probiotic feeding trials the ingested dose of propionibacteria can be in the 10E7 to 10E8 cfu/g of ingested material, which is significantly higher that the expected ingesting from Swiss

cheese, for example. No treatment specific, dose response related adverse effect of the consumption of the *Propionibacterium* strains was noted in these studies (Manter-Alhonen, 1995).

In addition to their presence in dairy products and potential use in probiotics, *Propionibacterium* species are natural constituents of a variety of so-called "living foods" which are claimed to have positive effects in the treatment of numerous ailments in humans (Manter-Alhonen, 1995). This is further evidence of the ubiquitous distribution of the species in the human diet.

Swiss cheese is an example of a *Propionibacterium freudenreichii* subsp. *shermanii* cultured milk product (see above). Rhodia Inc. has compared the degree of anti-microbial inhibition present in a *Propionibacterium freudenreichii* subsp. *shermanii* cultured skim milk (MicroGARD®) to that found in a typical commercial Swiss cheese. A Swiss cheese extract was prepared by mincing Swiss cheese with an appropriate buffered solution, filtering the mixture and analyzing the extract for both organic acids and Gram-negative bacteria inhibition using *Pseudomonas putida* as the indicator organism. The data indicate that a 30% w/v Swiss cheese extract contains the following organic acids:

- acetic acid 1100 ppm
- propionic acid 1900 ppm
- lactic acid 170 ppm
- butyric acid 20 ppm

This is roughly the same ratio of acids contained in the MicroGARD® product.

This same 30 % w/v Swiss cheese extract, when assayed for Gram-negative bacteria inhibition exhibited the same degree of inhibitory activity as a 3-4% solution of *Propionibacterium freudenrichii* subsp *shermanii* cultured skim milk. These data indicate that the anti-microbial activity of the cultured product is similar to that routinely consumed by consumers of Swiss cheese for centuries without adverse effect.

(2) Recent Safe History of Use in Food. *Propionibacterium freudenreichii* subsp. *shermanii* cultured skim milk and cultured dextrose MicroGARD® have been in commerce in the U.S. and Canada since the early 1980s, produced by Rhodia and its predecessors, Rhone-Poulenc and Wesman Foods. Based on requests for specific food uses, U.S. and Canadian regulatory agencies reviewed MicroGARD® for such uses. In 1983, the U.S. Food and Drug Administration issued a "no objection" letter to the use of MicroGARD® in cottage cheese. In 1987, the U.S. Department of Agriculture permitted the use of MicroGARD® in meat and poultry products that are permitted to contain dairy products. In 1994, Canada Health and Welfare issued a "no objection" letter to the use of MicroGARD® in all applicable food not covered by Canadian standards of identity. (See Appendix for each letter) . At all times, MicroGARD® manufacture and use has conformed to all requirements/conditions noted in the regulatory agencies' letters. Since 1983, MicroGARD® has been used as a natural microbial growth inhibitor at levels up to 2% (w/w) in a number of foods, including cheeses (cottage, cream, mozzarella, ricotta), pesto sauce, pizza sauce,

pasta, Queso Fresco, refrigerated salad dressings, fresh salsas, dried sausages (pepperoni, salami, summer), frozen and refrigerated yogurts, refrigerated tortillas, and sour cream. Additional proposed uses are in cereal bars, deli salads, hash brown potatoes, muffins, refrigerated soups, raw breakfast sausage, and scones. There has never been a reported case of adverse reaction to consuming foods containing the MicroGARD® products.

(3) Corroborating European Study. In addition to the scientifically documented safety of the *Propionibacterium freudenreichii* subsp. *shermanii* strain, the scientifically documented safe use of the organism in food products for centuries, and the safe use as probiotics for humans as well as animals, Rhodia has generated corroborating scientific evidence of the safety of the *Propionibacterium freudenreichii* subsp. *shermanii* cultured dextrose (nondairy MicroGARD®) in the course of developing a dossier for European Union registration. This corroborating data showed:

- that the product was not mutagenic when tested using *Salmonella typhimurium* strains TA 1535, TA 1537, TA 98 and TA 100 with and without metabolic activation;
- that the product was not a sensitizer in an oral antigenicity study to determine active systemic anaphylaxis in guinea pigs; and
- that no consistent treatment-related, dose-dependent adverse effects were reported in a 13 week rat feeding trial using male and female Wistar rats. The NOAEL for this study was the highest

concentration fed, *i.e.*, 5.0% equal to 3.7 and 4.1 g/kg bw/day in males and females, respectively. We note that the NOAEL value is approximately 100 times the estimated total per capita intake. (Buard, et.al., 2003).

(4) Probable Consumption/Effect of MicroGARD® in Diet. In connection with its determination, Rhodia requested Novigen Sciences, Inc. (Novigen) to conduct an estimated dietary intake assessment at the use levels (range of use of 0.2-2.0% w/w) for the present and proposed uses of MicroGARD®. The complete intake assessment conducted by Novigen at specific use levels for all present and proposed food uses of MicroGARD® is included in the Appendix attached hereto. Dietary intakes of the cultured product for the indicated food uses were estimated by Novigen from food consumption data collected by the U.S. Department of Agriculture (USDA). Estimates for the daily intake were completed for the overall U.S. population, for infants, for children 1 to 3 years of age, and for children 4 to 6 years of age.

Total intake on both a per capita and a per user basis (g/day) was calculated at the mean and the 90th percentile. Intakes were also expressed on a bodyweight basis (g/kg bw/day) for each population group estimated. The mean per capita dietary intake of MicroGARD® for the U.S. population is estimated at 1.5g/day or 0.03 g/kg bw/day. Per users, the mean daily MicroGARD® intake for the U.S. population is 1.7 g/day or 0.03 g/kg bw/day. At the 90th percentile, intake is 3.5 g/day or 0.06 g/kg bw/day per capita and is 3.7 g/day or 0.07 g/kg bw/day for users.

For infants under 1 year, the mean per capita dietary intake is 0.4 g/day or 0.04 g/kg bw/day, while the per user mean dietary intake is 0.8 g/day or 0.07 g/kg bw/day. At the 90th percentile, infant per capita dietary intake is 1.3 g/day or 0.11 g/kg bw/day, and per user mean intake is 1.7 g/day or 0.15 g/kg bw/day. Children ages 1 to 3 have mean per capita dietary intake estimates of 0.8 g/day or 0.04 g/kg bw/day, and per user intake of 0.8 g/day or 0.06 g/kg bw/day. At the 90th percentile, these children have a mean per capita intake of 1.9 g/day or 0.14 g/kg bw/day, and per user intake of 2.0 g/day or 0.14 g/kg bw/day.

Children ages 4 to 6 have a mean per capita dietary intake of 0.9 g/day or 0.05 g/kg bw/day, and mean per user intake of 1.0 g/day or 0.05 g/kg bw/day. At the 90th percentile, mean per capita intake of these children is 2.3 g/day or 0.11 g/kg bw/day, and per user intake is 2.3 g/day or 0.12 g/kg bw/day.

(B) Information That May Appear Inconsistent With GRAS Determination:

Rhodia is not aware of information that appears to be inconsistent with the determination of safety or general recognition of safety for the present or proposed uses of MicroGARD®.

(C) Expert Consensus for GRAS Determination:

As noted above, MicroGARD® is produced by culturing a GRAS substance, skim milk or dextrose, with a safe and suitable organism that is then standardized with a GRAS substance. Moreover, the culturing organism has been identified as

naturally occurring in food through the ages and is recognized to be safe for use in food as evidenced by the published studies and data referenced above. Indeed, the class of culturing organism is recognized, at 21 CFR 133.195, by FDA for its use in certain cheeses. Dating back to 1983, both U.S. and Canadian regulatory agencies have issued "no objection" letters to MicroGARD® use in foods, which has resulted in the use of MicroGARD® since that time in an ever expanding number of foods with no reported adverse effects.

Further, in 1996, after acquiring the company that originally formulated MicroGARD®, Rhodia's predecessor company, Rhone-Poulenc, convened a panel of scientific experts, qualified by their training and experience to evaluated the safety and general recognition of safety of ingredients used in food, to review MicroGARD®. In 2002, in anticipation of expanded uses of MicroGARD®, Rhodia again convened a qualified panel of scientific experts to review MicroGRAD®. In both instances, the panels of scientific experts confirmed Rhodia's determination of the safety and general recognition of safety of the present and proposed uses of MicroGARD®. (See Appendix). The panels drew no distinction, nor posed any safety concern between the forms of MicroGARD® (dairy and nondairy). Indeed, in both cases MicroGARD® is produced from GRAS substances using a safe and suitable culturing organism for food.

In making its determination, Rhodia's expert panel stated that it had "independently and critically evaluated" information relating to MicroGARD®. The information included a "comprehensive search of the scientific literature for safety, toxicity, efficacy and tolerance of MicroGARD®", as well as "information

and data on the chemical, physical, and antimicrobial properties, manufacture and processing, stability, conditions of anticipated use, estimated daily intakes resulting from these uses, and safety of MicroGARD®". The panel found that the culturing organism used to manufacture MicroGARD®, *Propionibacterium freudenreichii* subsp. *shermanii*, is "a non-pathogenic, non-toxigenic organism that has a long history of safe use in food, and is, therefore, safe and suitable for use in food." It also noted studies corroborating that MicroGARD® is not mutagenic or a sensitizer. Reference is also made by the panel to US and Canadian regulatory agency "no objection" letters, dating back to 1983, and to the demonstrated safe use of MicroGARD® in an ever increasing number of foods in the past nearly 20 years. Based on scientific procedures, supported by a significant history of recent safe food use, Rhodia's panel of scientific experts summarized its determination by stating that "MicroGARD® is safe and suitable for use in food as a natural microbial growth inhibitor".

Based on the information contained in the exemption claim, the above additional and supplementary information, and the information contained in the Appendix attached hereto, an ample basis exists to support Rhodia's determination of general recognition of safety of MicroGARD® for the present and proposed uses herein. Indeed, Rhodia's independent panel of scientific experts indicated a consensus of common knowledge of safety of the proposed uses of MicroGARD® among qualified scientists in concluding its review by determining that "The members of the Expert Panel, having independently and collectively critically evaluated the information summarized above and included in the

appendices to this report, unanimously conclude that MicroGARD®, when produced in accordance with current Good Manufacturing Practice and meeting appropriate food grade specifications, is safe for use in food as a natural microbial growth inhibitor, as specified herein."

The panel then addressed general recognition in the scientific community by stating "The members of the Expert Panel further conclude that MicroGARD®, produced in accordance with current Good Manufacturing Practice and meeting appropriate food grade specifications, is generally recognized as safe (GRAS), based on scientific procedures for use as a natural microbial growth inhibitor. This conclusion is supported by published and unpublished scientific literature, and is consistent with "no objection" letters for various food uses by USFDA, USDA, and Canada Health and Welfare."

Bibliography

1. Britz, T.J., and Riedel, K.H.J. 1995 Numerical evaluation of the species groupings among the classical propionibacteria. Lait 75, 309-314.
2. Buard A., Carlton, B.D., Floch F., Simon, G.S. 2003. Subchronic toxicity, mutagenicity and allergenicity studies with MicroGARD® 200, a cultured dextrose food product. Food and Chemical Toxicology, 41, 689-694.
3. Cummins, C.S., Johnson, J. L. (1986). Genus I. *Propionibacterium* Orla-Jensen 1909. In: Bergey's Manual of Systematic Bacteriology, Vol. 2 (P. H. A. Sneath, N.S. Mair, M.E. Sharpe, J.G. Holt, eds.). The Williams & Wilkins co., Baltimore, MD, USA.
4. Kosikowski, F. 1982. Origins, Movements and Potential in Cheese and Fermented Milk Foods, 2nd ed. F. V. Kosikowski and Associates, Brooktondale, NY.
5. Langsrud, T., and Reinbold, G. W. 1973. Flavor Development and Microbiology of Swiss Cheese – A Review. II. Starters, Manufacturing Processes and Procedures. J. Milk Food Technology, vol. 36. No. 11.
6. Mantere-Alhonen, S. 1995. Propionibacteria used as probiotics–A review. Lait, 75, 447-452.
7. Morgensen, G., Salminen, S., O'Brien, J., Ouwehand, A., Holzapfel, W., Short, C., Fonden, R., Miller, B.D., Donohue, D., Playne, M., Crittenden, Bianchi Salvadori, B., and Zink, R.. 2002. Inventory of Microorganisms with a Documented History of Use in Food. In: Health benefits and safety evaluation of certain food components. Bulletin of the International Dairy Federation 377/2002.

MICROGARD® GRAS NOTICE APPENDIX

INDEX TO INCLUDED ITEMS

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INDEPENDENT GENERALLY RECOGNIZED AS SAFE DETERMINATION OF

MicroGARD

July 2002

000042

Independent GRAS Determination of MicroGARD

1. Introduction

The undersigned, an independent panel of recognized experts (hereinafter, the Expert Panel), qualified by their scientific training and relevant national and international experience in evaluating the safety of food and food ingredients, were requested by Rhodia Inc. to review and affirm the generally recognized as safe (GRAS) status of MicroGARD for use in food as a natural microbial growth inhibitor. The members of the Expert Panel include Professor Joseph F. Borzelleca (Medical College of Virginia), Professor Bert N. LaDu (University of Michigan Medical School), and Professor Michael W. Pariza (University of Wisconsin). The qualifications of the members of the Expert Panel are evidenced in their curricula vitae, which appear in Appendix 1.

2. Basis for GRAS Status

Rhodia Inc. conducted a comprehensive search of the scientific literature for safety, toxicity, efficacy, and tolerance of MicroGARD and made this information available to the Expert Panel. In addition, Rhodia Inc. provided the Expert Panel with information and data on the chemical, physical, and antimicrobial properties, manufacture and processing, stability, conditions of anticipated use, estimated daily intakes resulting from these uses, and safety of MicroGARD. This information was consolidated by Rhodia Inc. in a document attached as Appendix 2 (the dossier). The Expert Panel members independently and critically evaluated the information, as well as other data and materials deemed appropriate or necessary, conferred as needed by telephone, and then met in Chicago, Illinois (08 April 2002) with technical representatives of Rhodia Inc. and other technical and legal experts. The Expert Panel critically evaluated all the available information and unanimously concluded that MicroGARD, manufactured in accordance with current Good Manufacturing Practice (GMP) and meeting appropriate food grade specifications, is GRAS, by scientific procedures for use in food as a natural microbial growth inhibitor, as specified herein, at levels not to exceed current GMP.

3. History of Use

MicroGARD is a product of lactic acid culture fermentation in skim milk, lactose, dextrose, or other safe and suitable food ingredients that is standardized with skim milk solids, maltodextrin, or other safe and suitable food ingredients. It has a demonstrated functionality in foods as a natural microbial growth inhibitor, being first commercialized for food use in the United States in July, 1983. MicroGARD is an antimicrobial agent used to maintain flavor and to retain freshness in a number of foods, including cheeses (cottage, cream, mozzarella, ricotta), pesto sauce, pizza sauce, fresh pasta, Queso Fresco, refrigerated salad dressing, fresh salsas, dried sausages (pepperoni, salami, summer), refrigerated tortillas, sour cream, and frozen and refrigerated yogurts.

Based on requests for specific food uses, domestic and international regulatory agencies have reviewed MicroGARD and authorized such uses. In 1983, the U.S. Food and Drug Administration issued a standard "no objection" letter to the use of MicroGARD in cottage cheese. In 1987, the U.S. Department of Agriculture permitted the use of MicroGARD in meat and poultry products that are permitted to contain dairy products. In 1994, Canada Health and Welfare issued a "no objection" letter to the use of MicroGARD in all applicable food not covered by Canadian standards of identity.

4. Description of MicroGARD

The Rhodia MicroGARD products subject to the panel's review are produced by lactic acid culture fermentation utilizing *Propionibacterium freudenreichii* subsp. *shermanii* in either skim milk or dextrose. Dairy MicroGARD (MicroGARD 100) is standardized with skim milk solids, while non-dairy MicroGARD (MicroGARD 200) is standardized with maltodextrin. Natural organic acids and metabolites contained in MicroGARD have been demonstrated in a variety of foods to inhibit spoilage microbial outgrowth, specifically Gram negative psychrotrophs and select yeast and molds.

In powdered form, the MicroGARD products have an off-white color, a slight cooked odor, and a buttermilk flavor. MicroGARD products typically have a pH of 7.0-7.3, with dairy MicroGARD having a moisture content of 2.9% and non-dairy MicroGARD having a moisture content of 2.1%. Typical MicroGARD microbiological analysis follows:

Standard Plate Count	Less than 2,500
Yeast & Mold	Less than 10
Lactobacillus	Less than 10
Coliforms	Negative
E. coli	Negative
Salmonella	Negative
Staphylococcus (C.P.)	Negative

5. Manufacture of MicroGARD

MicroGARD is manufactured in the United States by Northern Food and Dairy at a USDA inspected dairy plant (also inspected by the State of Minnesota Department of Agriculture). The plant is certified to process Grade A milk, in accordance with Food and Drug Administration and Interstate Milk Shippers standards. All methods of analyses utilized comply with Standard Methods for the Examination of Dairy Products of the American Public Health Association. Starter organisms used for production of MicroGARD are prepared by Rhodia Inc. and supplied to Northern Food and Dairy. To ensure purity of the inoculum, Rhodia sterilizes the medium used for starter production. All starter batches are thoroughly analyzed by Rhodia Inc. for possible contaminants prior to shipment.

In actual production, MicroGARD is manufactured through a specific time and temperature controlled fermentation of skim milk or dextrose with *Propionibacteria freudenreichii* subsp. *shermanii*. Skim milk or dextrose may be supplemented with small amounts of yeast extract and sodium acetate as incidental additives. The mixture is sterilized and cooled to an incubation temperature of 86° F. The pH is then lowered to 5.6-5.8 with lactic acid to minimize the outgrowth of contaminants. The mixture is then inoculated with frozen, concentrated cultures, prepared by Rhodia, Inc., and allowed to incubate for up to four days.

After the required incubation period, the pH is readjusted to approximately 6.0 with potassium hydroxide followed by fortification with safe and suitable solids, either Grade A skim milk or maltodextrin. The mixture is pasteurized, condensed, repasteurized and dried. MicroGARD is then packaged and stored in a cool, dry environment. A liquid form of MicroGARD is also produced, eliminating the drying stage. It is noted that after manufacture, all MicroGARD is tested for microbiological integrity by Northern Food and Dairy and by an independent certified laboratory prior to accepting the finished product.

6. Uses

MicroGARD is used as a natural microbial growth inhibitor in cheeses (cottage, cream, mozzarella, ricotta), pesto sauce, pizza sauce, fresh pasta, Queso Fresco, refrigerated salad dressings, fresh salsas, dried sausages (pepperoni, salami, summer), refrigerated tortillas, sour cream, and in frozen and refrigerated yogurt. Proposed MicroGARD food applications are in cereal bars, deli salads, hash brown potatoes, muffins, refrigerated soups, raw breakfast sausage, and scones. Present and potential uses are listed in specific detail in a dietary intake assessment document prepared for Rhodia Inc., a copy of which is contained in Appendix 2. MicroGARD levels of use for each food product are determined by, and in accordance with, current GMP. Current use levels and estimated use levels, however, indicate a range of use of 0.2-2.0% (w/w).

No information on self-limiting levels of use was noted.

7. Exposure

Dietary intakes of MicroGARD for the indicated food uses were estimated by Novigen Sciences, Inc. for Rhodia Inc. from food consumption data collected by the U.S. Department of Agriculture (USDA). Estimates for the daily intake were completed for the overall U.S. population, for infants, for children 1 to 3 years of age, and for children 4 to 6 years of age. The complete dietary intake assessment is included in Appendix 2.

Total intake of MicroGARD, on both a per capita and a per user basis (g/day), was calculated at the mean and the 90th percentile. Intakes were also expressed on a bodyweight basis (g/kg bw/day) for each population group estimated. The mean per capita dietary intake of MicroGARD for the US population is 1.5g/day or 0.03 g/kg bw/day. Per users, the mean daily MicroGARD intake for the US population is 1.7 g/day or 0.03 g/kg bw/day. At the 90th

percentile, MicroGARD intake is 3.5 g/day or 0.06 g/kg bw/day per capita, and is 3.7 g/day or 0.07 g/kg bw/day for users.

For infants under 1 year, the mean per capita dietary intake is 0.4 g/day or 0.04 g/kg bw/day, while the per user mean dietary intake is 0.8 g/day or 0.07 g/kg bw/day. At the 90th percentile, infant per capita dietary intake of MicroGARD is 1.3 g/day or 0.11 g/kg bw/day, and per user intake is 1.7 g/day or 0.15 g/kg bw/day.

Children ages 1 to 3 have mean per capita dietary intake of 0.8 g/day or 0.04 g/kg bw/day, and per user intake of 0.8 g/day or 0.06 g/kg bw/day. At the 90th percentile, these children have mean per capita MicroGARD intake of 1.9 g/day or 0.14 g/kg bw/day, and per user intake of 2.0 g/day or 0.14 g/kg bw/day.

Children ages 4 to 6 have mean per capita dietary MicroGARD intake of 0.9 g/day or 0.05 g/kg bw/day, and mean per user intake of 1.0 g/day or 0.05 g/kg bw/day. At the 90th percentile, mean per capita intake of these children is 2.3 g/day or 0.11 g/kg bw/day, and per user intake is 2.3 g/day or 0.12 g/kg bw/day.

8. Safety

The lactic acid producing source organism used in the culture fermentation to manufacture MicroGARD is *Propionibacterium freundenreichii* subsp. *shermanii*, This is a non-pathogenic, non-toxigenic organism that has a long history of safe use in food, and is, therefore, safe and suitable for use in food.

MicroGARD was not mutagenic when tested using *Salmonella typhimurium* strains TA 1535, TA 1537, TA 98 and TA 100, with and without metabolic activation.

MicroGARD was not a sensitizer in an oral antigencity study to determine active systemic anaphylaxis in guinea pigs.

MicroGARD was administered in the diet to male and female Wistar rats at dietary concentrations of 0, 0.5, 2.0, or 5.0% for 13 consecutive weeks. There were no consistent treatment-related, dose-dependent adverse effects reported. The NOAEL for this study was the highest concentration fed, 5.0% equal to 3.7 and 4.1 g/kg bw/day in males and females, respectively.

9. Summary

MicroGARD is a natural microbial growth inhibitor produced from *Propionibacterium freundenreichii* subsp. *shermanii*, a non-toxigenic and non-pathogenic harmless lactic acid producing bacteria that is safe and suitable for use in food based on its long history of safe use in food. MicroGARD is manufactured through controlled fermentation of skim milk or dextrose with *Propionibacteria freundenreichii* subsp. *shermanii*, a non-pathogenic, non-toxic organism that has a long history of safe use in food processing. Production is consistent with current Good Manufacturing Practice and the resultant product consistently meets rigorous specifications. MicroGARD is to be used as a natural microbial growth inhibitor in a variety of products including cheeses, sausages, tortillas and various dairy products including yogurt and sour cream. The 90th percentile per capita intake for users is estimated to be 3.7 g/day or 0.07 g/kg bw/day. MicroGARD is not mutagenic, is not a sensitizer and did not induce toxicity when fed to rats at the highest recommended concentration of 5.0%. MicroGARD is safe and suitable for use in food as a natural microbial growth inhibitor based on scientific procedures (experimentally-derived safety data), supported by a long history of recent safe food use.

10. Conclusions

The members of the Expert Panel, having independently and collectively critically evaluated the information summarized above and included in the appendices to this report, unanimously conclude that MicroGARD, when produced in accordance with current Good Manufacturing Practice and meeting appropriate food grade specifications, is safe for use in food as a natural microbial growth inhibitor, as specified herein.

The members of the Expert Panel further conclude that MicroGARD, produced in accordance with current Good Manufacturing Practice and meeting appropriate food grade specifications, is generally recognized as safe (GRAS), based on scientific procedures, for use as a natural microbial growth inhibitor. This conclusion is supported by published and unpublished scientific literature, and is consistent with "no objection" letters issued for various food uses by USFDA, USDA, and Canada Health and Welfare.

Joseph F. Borzelleca, Ph.D.
Professor Emeritus
Pharmacology & Toxicology
Medical College of Virginia

Michael W. Pariza, Ph.D.
Distinguished Professor
Food Microbiology & Toxicology
University of Wisconsin

Bert N. LaDu, Jr., M.D., Ph.D.
Emeritus Professor
Pharmacology
University of Michigan Medical School

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INDEPENDENT SAFETY EVALUATION OF MicroGARD®

(CULTURED DAIRY OR NON-DAIRY FOOD INGREDIENTS)

MARCH 1996

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INDEPENDENT SAFETY EVALUATION OF MicroGARD®

At the request of the sponsor, Rhone-Poulenc Inc., a Panel of independent experts reviewed the safety of MicroGARD® and evaluated the general recognition of safety of MicroGARD® under its intended conditions of use in food. The Panel included Professor Joseph F. Borzelleca, Ph.D., Department of Pharmacology and Toxicology of the Medical College of Virginia, Virginia Commonwealth University, (Chairman); Professor L. J. Filer, Jr., M.D., Ph.D., Department of Pediatrics, University of Iowa; and Distinguished Professor Michael W. Pariza, Ph.D., Food Research Institute, University of Wisconsin. Resumes of Panel members are appended hereto as Attachment 1.

Specifically, the Panel was asked, as recognized experts in the field qualified by their individual scientific training and experience, to evaluate the safety, through the adequacy of scientific procedures, of MicroGARD® under the conditions of its intended use in food as a natural microbial growth inhibitor. A comprehensive search of the scientific literature on MicroGARD® and related products was conducted. Rhone-Poulenc, Inc. provided Panel members with relevant information on MicroGARD® for their review. It contained information relative to the manufacture, composition, properties, food uses, levels of use, exposure, published studies, and unpublished studies regarding MicroGARD®. Panel members individually reviewed the materials submitted and other information deemed appropriate and conferred by telephone. The Panel was convened in Chicago, Illinois on November 28, 1995 to consider the safety of MicroGARD®. At this meeting, an oral presentation of explanatory and supplementary information was provided to the Panel by technical representatives of Rhone-Poulenc Inc.

Subsequent to the Panel's meeting, Rhone-Poulenc Inc. commissioned TAS, Inc. to conduct a comprehensive analysis of food intake to determine the potential exposure to MicroGARD® from natural sources, current applications, and proposed applications. The consumption analysis and all previous information provided to the Panel was included in the document "MicroGARD® Background Information February 29, 1996" prepared by Rhone-Poulenc Inc. The comprehensive document, attached hereto as Attachment 2, was provided to Panel members for their review.

FINDINGS

Based on a comprehensive review of available information, a thorough discussion of issues at the meeting, and its internal deliberations, the Panel made the following findings:

- MicroGARD® is a product of lactic acid culture fermentation, e.g. *Propionibacterium freudenreichii* subsp. *shermanii*, in skim milk, lactose, dextrose, or other safe and suitable food ingredients that is standardized with skim milk solids, maltodextrin, or other safe and suitable food ingredients. It is used, or proposed for use, but not limited to use, as a cultured dairy or non-dairy ingredient in refrigerated salad dressings, ricotta cheese, pizza sauces, salsas, soups, fruit juices, pastas, pasta sauces, confections, cottage cheese, bagels, and prepared sauces.

- MicroGARD® controls the outgrowth of a variety of spoilage organisms common to food products, including numerous Gram negative psychrotrophs, yeast, and molds;

- The lactic acid producing source organism used in the culture fermentation to manufacture MicroGARD® is *Propionibacterium freudenreichii* subsp. *shermanii*. This organism has a long history of safe use in food, including as a culture for the production of Swiss cheese;

- Based on its long history of use in food, the *Propionibacterium freudenreichii* subsp. *shermanii* is a safe and suitable harmless lactic acid bacteria for use in food;

- MicroGARD® as an ingredient has a history of safe use in food since 1983, especially as evidenced by its widespread and common use in cottage cheese, yogurt, and refrigerated salad dressings;

- MicroGARD® has been found to effectively inhibit the outgrowth of certain spoilage organisms at use levels from 0.1-2.0% in foods;

- The efficacy of MicroGARD® as a microbial growth inhibitor has been substantiated in a variety of foods, including cottage cheese, yogurt, sour cream, dips, cream cheese, frozen yogurt mix, refrigerated salad dressings and sauces, pizza sauce, bagels, fresh pasta, and confections;

- The Food and Drug Administration has specifically expressed no objection to the use of dairy solids MicroGARD® in cottage cheese, subject only to Good Manufacturing Practice (GMP) limitations;

- The Department of Agriculture has authorized the use of MicroGARD® in meat and poultry food products that are permitted to contain dairy products, subject only to GMP limitations;

- The Health Protection Branch of Health and Welfare Canada has specifically expressed no objection to the use of MicroGARD® at the proposed levels of use in all unstandardized foods in Canada;

- A comprehensive consumer consumption analysis by TAS, Inc. concluded that the mean intake of MicroGARD® from natural sources, current applications, and proposed applications is estimated to be 0.542 gms/person/day. TAS, Inc. states, and the Panel agrees, that the estimate is a substantial overstatement of likely MicroGARD® consumption, perhaps as much as tenfold, especially in light of Rhone-Poulenc, Inc.'s stated market expectations. Therefore, the Panel believes that total dietary exposure to MicroGARD® is extremely low and that the proposed uses of MicroGARD® will have an insignificant impact on overall dietary patterns. The complete TAS, Inc. intake analysis is included in Attachment 2.

- A critical review of the available information, including published and unpublished studies, supports the safety of the intended food uses of MicroGARD®. These studies and related articles regarding MicroGARD® are contained in Attachment 2;

- All components utilized to produce MicroGARD® are safe and suitable for use in food;

- MicroGARD® is produced utilizing GMPs.

CONCLUSIONS

Based on the information presented to it, its deliberations, the foregoing findings, relevant scientific procedures, and the collective scientific training and experience of its members, the Panel concluded that dairy and nondairy MicroGARD®, products of lactic acid culture fermentation grown in skim milk, lactose, dextrose, or other suitable food ingredients and standardized with skim milk solids, maltodextrin or other safe and suitable food ingredients, are safe. Further, the Panel concluded that dairy and nondairy

MicroGARD® are Generally Recognized As Safe (GRAS) for use in food as stated herein when used in accordance with good manufacturing practices (GMP) and in amounts not to exceed those reasonably required to accomplish the intended effect.

Professor Joseph F. Borzelleca, Ph.D.
Chairman — Date

Professor L. J. Filer, Jr., M.D., Ph.D. — Date

Professor Michael W. Pariza, Ph.D. — Date

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NOVIGEN SCIENCES, INC.
International

Reply to the U.S. Office

UNITED STATES
1730 Rhode Island Avenue NW
Ste. 1100, Washington, DC 20036
T (202) 293-5374 F (202) 293-5377
info@novigensci.com

UNITED KINGDOM
75 Graham Road
Malvern, Worcs, WR14 2HR
T (+44) 1684-588444 F (+44) 1684-588445
info@novigensci.co.uk

DIETARY INTAKE OF MicroGARD® FROM FOOD CONSUMPTION IN THE US

PREPARED FOR:
Rhodia, Inc.
259 Prospect Plains Road
CN 7500
Cranbury, NJ 08512-7500

PREPARED BY:
Novigen Sciences, Inc.
1730 Rhode Island Avenue, NW
Suite 1100
Washington, DC 20036

May 21, 2002

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DIETARY INTAKE OF MicroGARD® FROM FOOD CONSUMPTION IN THE US

At the request of Rhodia, Inc. (Rhodia), Novigen Sciences, Inc. (Novigen) has estimated the daily intake of MicroGARD® from selected foods. Intake estimates were completed for: (1) the overall US population, (2) infants, (3) children 1 to 3 years of age, and (4) children 4 to 6 years of age. Total daily intake of MicroGARD®, on both a *per capita* and "per user" basis, was reported at the mean and 90th percentile. "Per user" estimates are based only on the consumption data in USDA's Continuing Survey of Food Intakes by Individuals (CSFII) of persons who reported eating the selected foods on either day of the survey. *Per capita* estimates, in contrast, use all the data, including persons who did not report consumption of any of the specific foods during the survey.

I. METHODS

Dietary intakes were estimated using Novigen's Foods and Residue Evaluation Program (FARE™) software, which incorporates food consumption data from CSFII, conducted from 1994 through 1996, 1998. By combining food consumption data with proposed levels of MicroGARD® provided by Rhodia, FARE™ generates distributions of the estimated dietary intake of MicroGARD®.

Provided the ingredient /contaminant of interest is not an acute toxicant or teratogen, it is appropriate to average exposures over a longer period than one day. Therefore, Novigen used each respondent's food consumption averaged over the two days of the CSFII survey. For example, if someone reported consuming 100 grams of bread on day 1 and 150 grams of bread on day 2, his/her 2-day average bread consumption would be 125 grams (100+150/2).

A 2-day average typically overestimates long-term (chronic) intake; however, only 2 nonconsecutive days' worth of food consumption data are available in the most recent CSFII survey database. Although the 1989-91 CSFII included food consumption diaries on 3 nonconsecutive days, Novigen believes that rapidly evolving trends in diet and the pace of introduction of new foods call into question the representativeness of the older data for today's consumers.

For these analyses, the total intake was calculated by combining the existing uses and levels with the proposed uses and their corresponding levels (See Table 1 for full listing).

II. RESULTS

Tables 2 and 3 present the results of the intake analyses assuming the MicroGARD® additions summarized in Table 1. Both *per capita* and "per user" values are reported for the overall US population, infants, children 1 to 3 years of age, and children 4 to 6 years of age.

The mean *per capita* dietary intake of MicroGARD® for the US population is 1.5 g/day. Among "users", that is, persons who reported consuming the selected foods (see Appendix) in the CSFII, mean daily MicroGARD® intake for the US population is 1.7 g/day. At the 90th percentile, MicroGARD® intake is 3.5 g/day *per capita* and 3.7 g/day for "users."

Mean *per capita* and "per user" intake for infants is 0.4 and 0.8 g/day, respectively. *Per capita* intake at the 90th percentile for infants is approximately one third less than that of the US population (1.3 g/day vs 3.5 g/day). For infant "users", intake is 1.7 g/day at the 90th percentile. Results for children ages 1 to 3 are very similar to those of children ages 4 to 6. Mean *per capita* and "per user" intakes are 0.8 and 0.9 g/day for children ages 1 to 3. Similarly, children ages 4 to 6 had intake values of 0.9 and 1.0 g/day. The 90th percentile "per user" intakes for children ages 1 to 3 were 2.0 g/day, and 2.3 g/day for children ages 4 to 6.

When intake is expressed divided by bodyweight (Table 3), the mean *per capita* and "per user" dietary intakes of MicroGARD® for the US population are both 0.03 g/kg bw/day. At the 90th percentile, MicroGARD® intake is 0.06 g/kg bw/day *per capita* and 0.07 g/kg bw/day for "users." Infants' and young children's intakes, on a bodyweight basis, are higher than the US population MicroGARD® intake primarily because of their higher ratio of food intake to body size. Of the groups analyzed, children 1 to 3 years of age reported the highest intakes divided by body weight. The mean *per capita* and "per user" intakes are both 0.06 g/kg bw/day. At the 90th percentile, MicroGARD® intake is 0.14 g/kg bw/day for both *per capita* and "per user" estimates.

Table 1a

MicroGARD® Applications Provided by Rhodia

Product	MicroGARD Use Level (%w/w)	Product	MicroGARD Use Level (%w/w)
Cheese, cottage	0.1	Salsas, fresh	2.0
Cheese, cream	0.2	Sausages, dried:	
Cheese, mozzarella	0.5	Pepperoni	1.0
Cheese, ricotta	1.0	Salami	1.0
Pesto sauce	1.0	Summer Sausage	1.0
Pizza sauce	1.0	Tortillas, refrigerated	0.5
Pasta, fresh	1.0	Sour cream	0.15
Queso Fresco	1.0	Yogurt, frozen	0.2
Salad dressing, refrigerated	2.0	Yogurt, refrigerated	0.2

Table 1b
Proposed Food Applications

Product	MicroGARD Use Level (%w/w)
Refrigerated soups	1
Deli salads	1
Hash Brown Potatoes	1.5
Cereal Bars	1.5
Sausage, raw breakfast	2.0
Scones and muffins	2.0

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Table 2

Total Daily Estimated MicroGARD® Intake for the US Population 1994-1996, 1998 CSFII

	Per Capita (g/day)	Per User (g/day)
US Population		
Mean	1.5	1.7
90th Percentile	3.5	3.7
All Infants		
Mean	0.4	0.8
90th Percentile	1.3	1.7
Children 1 to 3		
Mean	0.8	0.9
90th Percentile	1.9	2.0
Children 4 to 6		
Mean	0.9	1.0
90th Percentile	2.3	2.3

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Table 3

Total Daily Estimated MicroGARD® Intake
US Population Divided by Bodyweight
1994-1996, 1998 CSFII

	Per Capita (g/kg bw/day)	Per User (g/kg bw/day)
US Population		
Mean	0.03	0.03
90th Percentile	0.06	0.07
All Infants		
Mean	0.04	0.07
90th Percentile	0.11	0.15
Children 1 to 3		
Mean	0.06	0.06
90th Percentile	0.14	0.14
Children 4 to 6		
Mean	0.05	0.05
90th Percentile	0.11	0.12

APPENDIX

LIST OF FOODS INCLUDED IN ANALYSES

APPENDIX

LIST OF FOODS INCLUDED IN ANALYSES

COTTAGE CHEESE AND RICOTTA CHEESE[1]

14200100	CHEESE, COTTAGE, NFS
14201010	CHEESE, COTTAGE, CREAMED
14201200	COTTAGE CHEESE, FARMER'S
14201500	CHEESE, RICOTTA
14202010	CHEESE, COTTAGE, W/ FRUIT
14202020	CHEESE, COTTAGE, W/ VEGETABLES
14203010	CHEESE, COTTAGE, DRY CURD
14203020	CHEESE, COTTAGE, SALTED, DRY CURD
14204010	CHEESE, COTTAGE, LOWFAT
14204020	CHEESE, COTTAGE, LOWFAT, W/ FRUIT
14204030	CHEESE, COTTAGE, LOWFAT, W/ VEGETABLES
14205010	CHEESE, COTTAGE, LOW SODIUM
14206010	CHEESE, COTTAGE, LOWFAT, LOW SODIUM
14207010	CHEESE, COTTAGE, LOWFAT, LACTOSE REDUCED
14610210	COTTAGE CHEESE, W/ GELATIN DESSERT & FRUIT
14610200	COTTAGE CHEESE, W/ GELATIN DESSERT
14610250	COTTAGE CHEESE W/ GELATIN DESSERT & VEGETABLES
58121610	DUMPLING, POTATO- OR CHEESE-FILLED
58122210	GNOCCHI, CHEESE
58122320	KNISH, CHEESE
58124210	PASTRY, CHEESE-FILLED
58124250	SPANAKOPITTA
58125120	SPINACH QUICHE, MEATLESS
58125180	CHEESE QUICHE, MEATLESS
58126130	TURNOVER, MEAT- AND CHEESE-FILLED, NO GRAVY
58126150	TURNOVER, MEAT- AND CHEESE-FILLED, TOMATO-BASED SAUCE
58130010	LASAGNA WITH MEAT AND/OR POULTRY
58130013	LASAGNA WITH MEAT, CANNED
58130020	LASAGNA WITH MEAT AND SPINACH
58130150	LASAGNA, WITH CHICKEN OR TURKEY, AND SPINACH
58130310	LASAGNA, MEATLESS
58130320	LASAGNA, MEATLESS, WITH SPINACH
58130610	LASAGNA WITH MEAT, WHOLE WHEAT NOODLES
58130950	LASAGNA, MEATLESS, SPINACH NOODLES
58131100	RAVIOLI, NS AS TO FILLING, NO SAUCE
58131110	RAVIOLI, NS AS TO FILLING, WITH TOMATO SAUCE
58131310	RAVIOLI, MEAT-FILLED, NO SAUCE
58131320	RAVIOLI, MEAT-FILLED, WITH TOMATO SAUCE OR MEAT SAUCE
58131323	RAVIOLI, MEAT-FILLED, WITH TOMATO SAUCE OR MEAT SAUCE, CA
58131510	RAVIOLI, CHEESE-FILLED, NO SAUCE
58131520	RAVIOLI, CHEESE-FILLED, WITH TOMATO SAUCE
58131523	RAVIOLI, CHEESE-FILLED, WITH TOMATO SAUCE, CANNED
58131530	RAVIOLI, CHEESE-FILLED, WITH MEAT SAUCE
58131600	RAVIOLI, CHEESE AND SPINACH-FILLED, WITH CREAM SAUCE
58132113	PASTA WITH TOMATO SAUCE AND CHEESE, CANNED
58132310	SPAGHETTI WITH TOMATO SAUCE AND MEATBALLS OR SPAGHETTI WI
58132360	SPAGHETTI WITH TOMATO SAUCE AND MEATBALLS, WHOLE WHEAT NO

[1] Only the cottage cheese portion of mixed dishes was included in the analyses

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58132713	PASTA WITH TOMATO SAUCE AND FRANKFURTERS OR HOT DOGS, CAN
58133110	MANICOTTI, CHEESE-FILLED, NO SAUCE
58133120	MANICOTTI, CHEESE-FILLED, WITH TOMATO SAUCE, MEATLESS
58133130	MANICOTTI, CHEESE-FILLED, WITH MEAT SAUCE
58133140	MANICOTTI, VEGETABLE- AND CHEESE-FILLED, WITH TOMATO SAUC
58134110	STUFFED SHELLS, CHEESE-FILLED, NO SAUCE
58134120	STUFFED SHELLS, CHEESE-FILLED, WITH TOMATO SAUCE, MEATLES
58134130	STUFFED SHELLS, CHEESE-FILLED, WITH MEAT SAUCE
58134610	TORTELLINI, MEAT-FILLED, WITH TOMATO SAUCE
58134613	TORTELLINI, MEAT-FILLED, WITH TOMATO SAUCE, CANNED
58134620	TORTELLINI, CHEESE-FILLED, MEATLESS, WITH TOMATO SAUCE
58134640	TORTELLINI, CHEESE-FILLED, MEATLESS, WITH VINAIGRETTE DRE
58134650	TORTELLINI, MEAT-FILLED, NO SAUCE
58134660	TORTELLINI, CHEESE-FILLED, WITH CREAM SAUCE
58134710	TORTELLINI, SPINACH-FILLED, WITH TOMATO SAUCE
58134720	TORTELLINI, SPINACH-FILLED, NO SAUCE
58134810	CANNELLONI, CHEESE- AND SPINACH-FILLED, NO SAUCE
58301010	LASAGNA WITH CHEESE, TOMATO SAUCE, VEGETABLE, DESSERT (FR

CREAM CHEESE[2]

14301010	CHEESE, CREAM
14303010	CHEESE, CREAM, LOWFAT
14410380	CHEESE, PROCESSED CREAM CHEESE PRODUCT, NONFAT
14420200	CHEESE SPREAD, CREAM CHEESE OR NEUFCHATEL BASE
53104500	CHEESECAKE
53104520	CHEESECAKE, DIET
53104550	CHEESECAKE WITH FRUIT
53104570	CHEESECAKE, DIET, WITH FRUIT
53104600	CHEESECAKE, CHOCOLATE
53104650	CHEESECAKE, CHOCOLATE, REDUCED FAT
53400200	BLINTZ, CHEESE-FILLED
53511500	DANISH PASTRY, WITH CHEESE, FAT FREE, CHOLESTEROL FREE
53610200	COFFEE CAKE, CRUMB OR QUICK-BREAD TYPE, CHEESE-FILLED
58111200	PUFFS, FRIED, CRAB MEAT AND CREAM CHEESE FILLED

MOZZARELLA CHEESE[3]

14107010	CHEESE, MOZZARELLA, NFS (INCLUDE PIZZA CHEESE)
14107020	CHEESE, MOZZARELLA, WHOLE MILK
14107030	CHEESE, MOZZARELLA, PART SKIM (INCL ""LOWFAT"")
14107040	CHEESE, MOZZARELLA, LOW SODIUM
14107060	CHEESE, MOZZARELLA, NONFAT OR FAT FREE
14410710	CHEESE, PROCESSED, MOZZARELLA, LOW SODIUM
14620300	PIZZA TOPPING FROM CHEESE PIZZA
14620310	PIZZA TOPPING FROM VEG PIZZA
14620320	PIZZA TOPPING FROM MEAT PIZZA
14620330	PIZZA TOPPING FROM MEAT & VEG PIZZA
27510710	PIZZABURGER (HAMBURGER, CHEESE, SAUCE), ON 1/2 BUN
27510720	PIZZABURGER (HAMBURGER, CHEESE, SAUCE), WHOLE BUN
58106210	PIZZA, CHEESE, NS AS TO TYPE OF CRUST
58106220	PIZZA, CHEESE, THIN CRUST
58106230	PIZZA, CHEESE, THICK CRUST (INCL ENGLISH MUFFIN)

[2] Only the cream cheese portion of mixed dishes was included in the analyses

[3] Only the mozzarella cheese portion of mixed dishes was included in the analyses

APPENDIX (CONT'D)

58106310	PIZZA, CHEESE, W/ VEG, NS AS TO TYPE OF CRUST
58106320	PIZZA, CHEESE, W/ VEGETABLES, THIN CRUST
58106330	PIZZA, CHEESE, W/ VEGETABLES, THICK CRUST
58106360	PIZZA, CHEESE, W/ FRUIT, THICK CRUST
58106510	PIZZA W/ MEAT, NS AS TO TYPE OF CRUST
58106520	PIZZA W/ MEAT, THIN CRUST
58106530	PIZZA W/ MEAT, THICK CRUST
58106710	PIZZA W/ MEAT & VEG, NS AS TO TYPE OF CRUST
58106720	PIZZA W/ MEAT & VEGETABLES, THIN CRUST
58106730	PIZZA W/ MEAT & VEGETABLES, THICK CRUST
58106740	PIZZA W/ MEAT & FRUIT, NS AS TO TYPE OF CRUST
58106750	PIZZA W/ MEAT & FRUIT, THIN CRUST
58106760	PIZZA W/ MEAT & FRUIT, THICK CRUST
58106780	PIZZA,W/MEAT & VEGETABLES,LOW FAT, THIN CRUST
58106810	PIZZA W/ BEANS & VEGETABLES, NS AS TO TYPE OF CRUST
58106820	PIZZA W/ BEANS & VEG, THIN CRUST (INCL TACO PIZZA)
58106830	PIZZA W/ BEANS & VEG, THICK CRUST (INCL TACO PIZZA)
58106900	PIZZA W/ SEAFOOD, NS TYPE OF CRUST
58106910	PIZZA W/ SEAFOOD, THIN CRUST
58106920	PIZZA W/ SEAFOOD, THICK CRUST
58107210	WHITE PIZZA, NS AS TO TYPE OF CRUST
58107220	WHITE PIZZA, THIN CRUST
58107230	WHITE PIZZA, THICK CRUST
58108000	CALZONE, W/ CHEESE, MEATLESS (INCL STROMBOLI)
58108010	CALZONE, W/ MEAT & CHEESE (INCLUDE STROMBOLI)
58108030	PANZEROTTI W/ MEAT, VEGETABLES & CHEESE
58108040	PANZEROTTI W/ VEGETABLES & CHESSE
58108050	PIZZA ROLLS (INCLUDE PIZZA BITES)
58130010	LASAGNA W/ MEAT AND/OR POULTRY
58130013	LASAGNA W/ MEAT, CANNED
58130020	LASAGNA, W/ MEAT & SPINACH
58130150	LASAGNA W/ CHIC OR TURKEY, & SPINACH
58130310	LASAGNA, MEATLESS
58130320	LASAGNA, MEATLESS, W/ SPINACH
58130610	LASAGNA W/ MEAT, WHOLE WHEAT NOODLES
58130810	LASAGNA, MEATLESS, WHOLE WHEAT NOODLES
58130910	LASAGNA W/ MEAT, SPINACH NOODLES
58131510	RAVIOLI, CHEESE-FILLED, NO SAUCE
58131520	RAVIOLI, CHEESE-FILLED, W/ TOMATO SAUCE
58131523	RAVIOLI, CHEESE-FILLED, W/ TOMATO SAUCE, CANNED
58131530	RAVIOLI, CHEESE-FILLED, W/ MEAT SAUCE
58131600	RAVIOLI, CHEESE&SPINACH-FILLED, W/ CREAM SAUCE
58133110	MANICOTTI, CHEESE-FILLED, NO SAUCE
58133120	MANICOTTI, CHEESE-FILLED, W/ TOMATO SAUCE, MEATLESS
58133130	MANICOTTI, CHEESE-FILLED, W/ MEAT SAUCE
58133140	MANICOTTI, VEG- & CHEESE-FILLED, W/TOM SCE,MEATLESS
58134110	STUFFED SHELLS, CHEESE-FILLED, NO SAUCE
58134120	STUFFED SHELLS, CHEESE-FILLED, W/ TOM SC, MEATLESS
58134130	STUFFED SHELLS, CHEESE-FILLED, W/ MEAT SAUCE
58134160	STUFFED SHELL, CHEESE & SPINACH FILLED, NO SAUCE
58134620	TORTELLINI, CHEESE-FILLED, MEATLESS, W/TOMATO SAUCE
58134623	TORTELLINI,CHEESE-FILLED,MEATLESS,W/TOMATO SAUCE,CANNED
58134630	TORTELLINI, CHEESE, W/ VEGETABLES & DRESSING
58134640	TORTELLINI, CHEESE-FILLED, MEATLESS, W/ VINAIGRETTE

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58134660	TORTELLINI, CHEESE-FILLED, W/ CREAM SAUCE
58134680	TORTELLINI, CHEESE-FILLED, NO SAUCE
58134810	CANNELONI, CHEESE & SPINACH-FILLED, NO SAUCE
58100120	BURRITO W/ BEEF, BEANS, & CHEESE
58100130	BURRITO W/ BEEF & CHEESE, NO BEANS
58100140	BURRITO W/ BEEF, BEANS, CHEESE, & SOUR CREAM
58100220	BURRITO W/ CHICKEN, BEANS, & CHEESE
58100230	BURRITO W/ CHICKEN & CHEESE
58100320	BURRITO W/ BEANS & CHEESE, MEATLESS
58100340	BURRITO W/ EGGS, SAUSAGE, CHEESE AND VEGETABLES
58100350	BURRITO W/ EGGS & CHEESE,NO BEANS (INCL BREAKFAST B
58100360	CHILAQUILES,TORTILLA CASSEROLE W/ SALSA,CHEESE, EGG
58100520	ENCHILADA W/ BEEF, BEANS, & CHEESE
58100530	ENCHILADA W/ BEEF & CHEESE, NO BEANS
58100560	ENCHILADA W/ HAM & CHEESE, W/O BEANS
58100620	ENCHILADA W/ CHICKEN, BEANS & CHEESE, TOMATO SAUCE
58100630	ENCHILADA W/ CHICKEN & CHEESE, NO BEANS,TOMATO SCE
58100720	ENCHILADA W/ BEANS & CHEESE, MEATLESS
58100800	ENCHILADA W/ CHEESE, MEATLESS, NO BEANS
58101300	TACO/TOSTADA W/ BEEF, CHEESE, LETTUCE
58101320	TACO / TOSTADA W/ BEEF,CHEESE,LETTUCE, TOMATO,SALSA
58101350	TACO W/BEEF,CHEESE,LETTUCE,TOMATO,SOUR CREAM
58101400	SOFT TACO W/ BEEF,CHEESE,& LETTUCE(INCL TACO BELL)
58101450	SOFT TACO W/ CHICKEN, CHEESE & LETTUCE
58101520	TACO / TOSTADA W/ CHICKEN,CHEESE,LETTUCE,TOM,SALSA
58101720	TACO / TOSTADA W/ BEANS,CHEESE,LETTUCE,TOM,SALSA
58101730	TACO OR TOSTADA W/ BEANS,CHEESE,MEAT,LETT,TOM,SALSA
58101910	TACO SALAD W/ BEEF & CHEESE, CORN CHIPS
58101930	TACO SALAD W/ BEEF & CHEESE, FRIED FLOUR TORTILLA
58101940	TACO SALAD, MEATLESS,W/CHEESE, FRIED FLOUR TORTILLA
58104080	NACHOS W/ BEEF, BEANS, CHEESE & SOUR CREAM
58104090	NACHOS W/ CHEESE & SOUR CREAM
58104100	NACHOS W/ CHEESE, MEATLESS, NO BEANS
58104120	NACHOS W/ BEANS & CHEESE
58104130	NACHOS W/ BEEF, BEANS & CHEESE
58104140	NACHOS W/ BEEF & CHEESE
58104180	NACHOS W/BEEF,BEANS,CHEESE,TOMATOES & ONIONS
58104250	NACHOS WITH CHICKEN/TURKEY & CHEESE
58104260	CHALUPAS W/ BEANS,CHEESE,LETTUCE AND TOMATO
58104310	CHALUPAS W/ BEANS, CHICKEN & CHEESE
58104490	CHIMICHANGA, NFS
58104510	CHIMICHANGA W/ BEEF, CHEESE, LETTUCE AND TOMATO
58104520	CHIMICHANGA W/ BEANS& CHEESE, NO MEAT,LETTUCE&TOM
58104530	CHIMICHANGA W/ CHICKEN & CHEESE
58104710	QUESADILLA W/ CHEESE, MEATLESS
58104730	QUESADILLA W/ MEAT & CHEESE
58105100	PUPUSA, CHEESE-FILLED

PESTO SAUCE

58147100	PASTA W/ PESTO SAUCE
81302070	PESTO SAUCE

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PIZZA SAUCE

27510710	PIZZABURGER (HAMBURGER, CHEESE, SAUCE), ON 1/2 BUN
27510720	PIZZABURGER (HAMBURGER, CHEESE, SAUCE), WHOLE BUN
58106210	PIZZA, CHEESE, NS AS TO TYPE OF CRUST
58106220	PIZZA, CHEESE, THIN CRUST
58106230	PIZZA, CHEESE, THICK CRUST (INCL ENGLISH MUFFIN)
58106310	PIZZA, CHEESE, W/ VEG, NS AS TO TYPE OF CRUST
58106320	PIZZA, CHEESE, W/ VEGETABLES, THIN CRUST
58106330	PIZZA, CHEESE, W/ VEGETABLES, THICK CRUST
58106360	PIZZA, CHEESE, W/ FRUIT, THICK CRUST
58106510	PIZZA W/ MEAT, NS AS TO TYPE OF CRUST
58106520	PIZZA W/ MEAT, THIN CRUST
58106530	PIZZA W/ MEAT, THICK CRUST
58106710	PIZZA W/ MEAT & VEG, NS AS TO TYPE OF CRUST
58106720	PIZZA W/ MEAT & VEGETABLES, THIN CRUST
58106730	PIZZA W/ MEAT & VEGETABLES, THICK CRUST
58106740	PIZZA W/ MEAT & FRUIT, NS AS TO TYPE OF CRUST
58106750	PIZZA W/ MEAT & FRUIT, THIN CRUST
58106760	PIZZA W/ MEAT & FRUIT, THICK CRUST
58106780	PIZZA,W/MEAT & VEGETABLES,LOW FAT, THIN CRUST
58106810	PIZZA W/ BEANS & VEGETABLES, NS AS TO TYPE OF CRUST
58106820	PIZZA W/ BEANS & VEG, THIN CRUST (INCL TACO PIZZA)
58106830	PIZZA W/ BEANS & VEG, THICK CRUST (INCL TACO PIZZA)
58106900	PIZZA W/ SEAFOOD, NS TYPE OF CRUST
58106910	PIZZA W/ SEAFOOD, THIN CRUST
58106920	PIZZA W/ SEAFOOD, THICK CRUST
58107000	GROUND BEEF W/ TOMATO SAUCE ON A PIZZA CRUST
58107030	PIZZA, NO CHEESE, NS AS TO TYPE OF CRUST
58107050	PIZZA, NO CHEESE, THIN CRUST
58107100	PIZZA, NO CHEESE, THICK CRUST
58108000	CALZONE, W/ CHEESE, MEATLESS (INCL STROMBOLI)
58108010	CALZONE, W/ MEAT & CHEESE (INCLUDE STROMBOLI)
58108030	PANZEROTTI W/ MEAT, VEGETABLES & CHEESE
58108040	PANZEROTTI W/ VEGETABLES & CHESSE
58108050	PIZZA ROLLS (INCLUDE PIZZA BITES)
58109000	ITALIAN PIE, MEATLESS (INCL PRIAZZO FLORENTINE)
58109010	ITALIAN PIE W/ BEEF (INCL PRIAZZO ROMA & MILANO)

PASTA, "FRESH"[4]

27351060	SHRIMP & PASTA GARDEN SALAD W/ TOM/CAR, NO DRESSING
28331110	LAMB, PASTA & VEGETABLE SOUP, P.R.
41601060	BEANSOUPW/MACARONI&MEAT(INCL PASTA E FAGIOLE W/MEAT
41601090	BEAN SOUP W/ MACARONI (INCL PASTA E FAGIOLI)
56101000	MACARONI, COOKED, NS AS TO ADDED FAT
56101010	MACARONI, COOKED, NO FAT ADDED
56101030	MACARONI, COOKED, FAT ADDED
56102000	MACARONI, WHOLE WHEAT, COOKED, NS AS TO ADDED FAT
56102010	MACARONI, WHOLE WHEAT, NO FAT ADDED
56102020	MACARONI, WHOLE WHEAT, FAT ADDED
56103000	MACARONI, SPINACH, NS AS TO ADDED FAT
56103010	MACARONI, SPINACH, NO FAT ADDED

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[4] CSFII does not distinguish between pasta sold dried or fresh/refrigerated. Novigen included all pasta except for dishes specifically identified as "canned". Only the pasta portion of mixed dishes was included in the analyses.

APPENDIX (CONT'D)

56103020	MACARONI, SPINACH, FAT ADDED
56104000	MACARONI,CKD,VEGETABLE,NS AS TO FAT ADDED
56104010	MACARONI,COOKED,VEGETABLE,FAT NOT ADDED IN COOKING
56104020	MACARONI,COOKED,VEGETABLE, FAT ADDED IN COOKING
56112000	NOODLES, COOKED, NS AS TO ADDED FAT
56112010	NOODLES, COOKED, NO FAT ADDED
56112030	NOODLES, COOKED, FAT ADDED
56113000	NOODLES, COOKED,WHOLE WHEAT,NS AS TO FAT ADDED
56113010	NOODLES, WHOLE WHEAT, COOKED, NO FAT ADDED
56113990	NOODLES, COOKED, SPINACH, NS AS TO FAT
56114000	NOODLES, SPINACH, COOKED, NO FAT ADDED
56114020	NOODLES, COOKED, SPINACH, FAT ADDED
56130000	SPAGHETTI, COOKED, NS AS TO ADDED FAT
56130010	SPAGHETTI, COOKED, NO FAT ADDED
56131000	SPAGHETTI, COOKED, FAT ADDED
56132000	SPAGHETTI,COOKED, HIGH PROTEIN(ASSUME NO FAT ADDED)
56132990	SPAGHETTI, COOKED, WHOLE WHEAT, NS AS TO ADDED FAT
56133000	SPAGHETTI, COOKED, WHOLE WHEAT, NO FAT ADDED
56133010	SPAGHETTI, COOKED, WHOLE WHEAT, FAT ADDED
56139990	PASTA, COOKED, CORN-BASED, NS AS TO FAT ADDED
56140000	PASTA, COOKED, CORN-BASED, NO FAT ADDED
58130010	LASAGNA W/ MEAT AND/OR POULTRY
58130020	LASAGNA, W/ MEAT & SPINACH
58130150	LASAGNA W/ CHIC OR TURKEY, & SPINACH
58130310	LASAGNA, MEATLESS
58130320	LASAGNA, MEATLESS, W/ SPINACH
58130610	LASAGNA W/ MEAT, WHOLE WHEAT NOODLES
58130810	LASAGNA, MEATLESS, WHOLE WHEAT NOODLES
58130910	LASAGNA W/ MEAT, SPINACH NOODLES
58130950	LASAGNA, MEATLESS, SPINACH NOODLES
58131100	RAVIOLI, FILLING NS, NO SAUCE
58131110	RAVIOLI, FILLING NS, TOMATO SAUCE
58131310	RAVIOLI, MEAT-FILLED, NO SAUCE
58131320	RAVIOLI, MEAT-FILLED, W/ TOMATO OR MEAT SAUCE
58131510	RAVIOLI, CHEESE-FILLED, NO SAUCE
58131520	RAVIOLI, CHEESE-FILLED, W/ TOMATO SAUCE
58131530	RAVIOLI, CHEESE-FILLED, W/ MEAT SAUCE
58131600	RAVIOLI, CHEESE&SPINACH-FILLED, W/ CREAM SAUCE
58132110	SPAGHETTI W/ TOMATO SAUCE, MEATLESS
58132310	SPAGHETTI W/TOMAT SAUCE & MEAT SAUCE
58132350	SPAGHETTI, WHOLE WHEAT, W/ TOMATO SAUCE, MEATLESS
58132360	SPAGHETTI, WHOLE WHEAT, W/ TOMATO & MEAT SAUCE
58132450	SPAGHETTI W/ TOM SAUCE, MEATLESS, SPINACH NOODLES
58132460	SPAGHETTI W/ TOMATO & MEAT SAUCE, SPINACH NOODLES
58132710	SPAGHETTI W/ TOMATO SAUCE & FRANKFURTERS/HOT DOG
58132800	SPAGHETTI W/ CLAM SAUCE, NS AS TO RED OR WHITE
58132810	SPAGHETTI W/ RED CLAM SAUCE
58132820	SPAGHETTI W/ WHITE CLAM SAUCE
58132910	SPAGHETTI W/ TOMATO SAUCE & CHICKEN OR TURKEY
58133110	MANICOTTI, CHEESE-FILLED, NO SAUCE
58133120	MANICOTTI, CHEESE-FILLED, W/ TOMATO SAUCE, MEATLESS
58133130	MANICOTTI, CHEESE-FILLED, W/ MEAT SAUCE
58133140	MANICOTTI, VEG- & CHEESE-FILLED, W/TOM SCE,MEATLESS
58134110	STUFFED SHELLS, CHEESE-FILLED, NO SAUCE

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APPENDIX (CONT'D)

58134120	STUFFED SHELLS, CHEESE-FILLED, W/ TOM SC, MEATLESS
58134130	STUFFED SHELLS, CHEESE-FILLED, W/ MEAT SAUCE
58134160	STUFFED SHELL, CHEESE & SPINACH FILLED, NO SAUCE
58134210	STUFFED SHELLS, W/ CHICKEN, W/ TOM SCE
58134310	STUFFED SHELLS, W/ FISH &/OR SHELLFISH, W/ TOM SCE
58134610	TORTELLINI, MEAT-FILLED, W/ TOMATO SAUCE
58134620	TORTELLINI, CHEESE-FILLED, MEATLESS, W/TOMATO SAUCE
58134630	TORTELLINI, CHEESE, W/ VEGETABLES & DRESSING
58134640	TORTELLINI, CHEESE-FILLED, MEATLESS, W/ VINAIGRETTE
58134650	TORTELLINI, MEAT-FILLED, NO SAUCE
58134660	TORTELLINI, CHEESE-FILLED, W/ CREAM SAUCE
58134680	TORTELLINI, CHEESE-FILLED, NO SAUCE
58134710	TORTELLINI, SPINACH-FILLED, W/ TOMATO SAUCE
58134720	TORTELLINI, SPINACH-FILLED, NO SAUCE
58134810	CANNELONI, CHEESE & SPINACH-FILLED, NO SAUCE
58135110	CHOW FUN NOODLES W/ MEAT & VEGETABLES
58135120	CHOW FUN NOODLES W/ VEGETABLES, MEATLESS
58136110	LO MEIN, NFS
58136120	LO MEIN, MEATLESS
58136130	LO MEIN WITH SHRIMP
58140110	SPAGHETTI W/ CORNED BEEF, P.R.
58140310	MACARONI W/ TUNA, P.R. (MACARRONES CON ATUN)
58145110	MACARONI OR NOODLES W/ CHEESE
58145114	MACARONI/NOODLES W/ CHEESE, MADE FROM DRY MIX
58145115	MACARONI/NOODLES W/CHEESE, FROM MIX W/PREPARED CHEESE SAUCE
58145120	MACARONI OR NOODLES W/ CHEESE & TUNA
58145130	MACARONI OR NOODLES W/ CHEESE & BEEF
58145140	MACARONI OR NOODLES W/ CHEESE & TOMATO
58145150	MACARONI W/ CHEESE & HAM
58145160	MACARONI/NOODLES W/ CHEESE & FRANKFURTER/HOT DOG
58145170	MACARONI & CHEESE MADE W/ EGG
58145190	MACARONI W/ CHEESE & CHICKEN
58146100	PASTA W/ TOMATO SAUCE, MEATLESS
58146110	PASTA W/ MEAT SAUCE (INCLUDE AMER CHOP SUEY)
58146120	PASTA W/ CHEESE & MEAT SAUCE
58146130	PASTA W/ CARBONARA SAUCE
58146150	PASTA W/ CHEESE & TOMATO SAUCE, MEATLESS
58146300	PASTA, WHOLE WHEAT, WITH MEAT SAUCE
58146310	PASTA, WHOLE WHEAT, W/ TOMATO SAUCE, MEATLESS
58147100	PASTA W/ PESTO SAUCE
58147110	MACARONI OR NOODLES W/ BEANS & TOMATO SAUCE
58147310	MACARONI, CREAMED
58147330	MACARONI, CREAMED, W/ CHEESE
58147350	MACARONI, CREAMED, W/ VEGETABLES
58147510	FLAVORED PASTA (INCL LIPTON BEEF, CHICKEN FLAVORS)
58148110	MACARONI SALAD
58148120	MACARONI SALAD W/ EGG
58148130	MACARONI SALAD W/ TUNA
58148140	MACARONI SALAD W/ CRAB MEAT
58148150	MACARONI SALAD W/ SHRIMP
58148160	MACARONI SALAD W/ TUNA & EGG
58148170	MACARONI SALAD W/ CHICKEN
58148180	MACARONI SALAD W/ CHEESE (INCL MADE W/ CELERY, CUCU
58148500	PASTA SALAD (MACARONI OR NOODLES, VEG, DRESSING)

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58148550 PASTA SALAD W/ MEAT (MACARONI, VEG, MEAT, DRESSING)
58148600 PASTA TETRAZZINI,DRY MIX,PREPARED W/ WATER
58149110 NOODLE PUDDING (INCLUDE KUGEL)
58149160 NOODLE PUDDING,W/ MILK
58149210 SOMEN SALAD W/ NOODLE, LETTUCE,

QUESO FRESCO
14133000 QUESO FRESCO (HISPANIC-STYLE FARMER CHEESE)

SALAD DRESSING, "REFRIGERATED"[5]
83100100 SALAD DRESSING, NFS
83101000 BLUE OR ROQUEFORT CHEESE DRESSING
83101500 BACON DRESSING (HOT)
83101600 BACON & TOMATO DRESSING
83102000 CAESAR DRESSSING
83103000 COLESLAW DRESSSING
83103500 FETA CHEESE SALAD DRESSING
83104000 FRENCH DRESSSING
83105000 FRUIT DRESSING W/ FRUIT JUICE & CREAM
83105100 FRUIT DRESSING, MADE W/ HONEY, OIL, WATER
83105500 HONEY MUSTARD DRESSING
83106000 ITALIAN DRESSING, W/ VINEGAR & OIL
83107000 MAYONNAISE, REGULAR
83107100 MAYONNAISE, MADE W/ YOGURT (INCLUDE YOGANNAISE)
83107200 MAYONNAISE, MADE W/ TOFU
83108000 MAYONNAISE, IMITATION
83108100 MAYONNAISE, IMITATION, NO CHOLESTEROL
83109000 RUSSIAN DRESSING
83110000 MAYONNAISE-TYPE SALAD DRESSING
83110010 MAYONNAISE-TYPE SALAD DRESSING, CHOLESTEROL-FREE
83111000 BOILED, COOKED-TYPE DRESSING
83112000 GREEN GODDESS DRESSING
83112500 CREAMY DRESSING, W/SOUR CREAM/BUTTERMILK & OIL
83112600 CREAM CHEESE DRESSING
83112900 MILK, VINEGAR & SUGAR DRESSING
83112950 POPPY SEED DRESSING
83112960 PEPPERCORN DRESSING
83112980 CELERY SEED DRESSING
83112990 SESAME DRESSING
83113000 SWEET & SOUR DRESSING
83114000 THOUSAND ISLAND DRESSING
83115000 YOGURT DRESSING
83200100 SALAD DRESSING, LOW CALORIE, NFS
83200500 BACON & TOMATO DRESSING, LOW CALORIE
83201000 BLUE OR ROQUEFORT CHEESE DRESSING, LOW CALORIE
83201050 BLUE OR ROQUEFORT CHEESE DRESSING, REDUCED CALORIE
83201200 BLUE/ROQUEFORT CHEESE DRESSING,RED CAL,NO FAT/CHOL
83201400 COLESLAW DRESSING, REDUCED CALORIE
83202000 FRENCH DRESSING, LOW CALORIE
83202010 FRENCH DRESSING, REDUCED CALORIE,FAT-FREE,CHOL-FREE
83202020 FRENCH DRESSING, REDUCED CALORIE

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[5] CSFII does not distinguish between dressings sold refrigerated or processed/bottled. Novigen included all dressings.

83203000	CAESAR DRESSING, LOW CALORIE
83203250	MAYONNAISE-TYPE SALAD DRESSING, FAT-FREE
83204000	MAYONNAISE, LOW CALORIE OR DIET
83204010	MAYONNAISE, LOW CALORIE OR DIET, LOW SODIUM
83204020	MAYONNAISE, REDUCED-CALORIE/DIET, CHOLESTEROL-FREE
83204050	MAYONNAISE-TYPE SALAD DRESSING, LOW CALORIE
83204060	MAYONNAISE-TYPE SALAD DRESSING,DIET,NO CHOLESTEROL
83205000	ITALIAN DRESSING, LOW CALORIE
83205450	ITALIAN DRESSING, REDUCED CALORIE
83205500	ITALIAN DRESSING, REDUCED CALORIE, FAT-FREE
83206000	RUSSIAN DRESSING, LOW CALORIE
83207000	THOUSAND ISLAND DRESSING, LOW CALORIE
83207100	THOUSAND ISLAND DRSG,REDUCED CAL,FAT-FREE,CHOL-FREE
83208000	VINEGAR, SUGAR & WATER DRESSING
83208500	KOREAN DRESSING OR MARINADE
83209000	MILK, VINEGAR & ARTIFICIAL SWEETENER DRESSING
83210000	CREAMY DRESSING W/ BUTTERMILK, NS LOW/REDUCED CAL
83210050	CRMY DRSG W/ SOUR CRM &/ BUTTERMILK & OIL, LOW CAL
83210100	CRMY DRSG W/ SOUR CRM &/ BUTTERMILK & OIL, RED CAL
83210200	CRMY DRSG W/SOUR CRM&/BTTRMILK,RED CAL,NOFAT/CHOL
83210250	CRMY DRSG W/SOUR CRM&/BUTTRMILK&OIL,RED CAL,NOCHOC
83220000	SALAD DRESSING, LOW CALORIE, OIL-FREE

SALSA, "FRESH"[6]

74402100	SALSA, NFS
74402110	SALSA, RED, UNCOOKED (INCL PICO DE GALLO)
74402150	SALSA, RED, CKD, NOT HOM (INCL TACO, CREOLE, PICANTE SAUCES)
74402200	SALSA, RED, COOKED, HOMEMADE (INCL DE CHILE ROJO)
58100360	CHILAQUILES,TORTILLA CASSEROLE W/ SALSA,CHEESE, EGG
58100600	ENCHILADA W/ CHICKEN, TOMATO-BASE SAUCE
58100610	ENCHILADA W/ CHICKEN & BEANS, TOMATO-BASE SAUCE
58100620	ENCHILADA W/ CHICKEN, BEANS & CHEESE, TOMATO SAUCE
58100630	ENCHILADA W/ CHICKEN & CHEESE, NO BEANS,TOMATO SCE
58100900	ENCHILADA W/ SEAFOOD, TOMATO SAUCE
58101310	TACO OR TOSTADA W/ BEEF, LETTUCE, TOMATO & SALSA
58101320	TACO / TOSTADA W/ BEEF,CHEESE,LETTUCE, TOMATO,SALSA
58101510	TACO / TOSTADA W/ CHICKEN/TURKEY,LETTUCE,TOM,SALSA
58101520	TACO / TOSTADA W/ CHICKEN,CHEESE,LETTUCE,TOM,SALSA
58101710	TACO / TOSTADA W/ BEANS,MEATLESS,LETTUCE,TOM,SALSA
58101720	TACO / TOSTADA W/ BEANS,CHEESE,LETTUCE,TOM,SALSA
58101730	TACO OR TOSTADA W/ BEANS,CHEESE,MEAT,LETT,TOM,SALSA

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[6] CSFII does not distinguish between salsa sold fresh or processed. Novigen included all salsa, including the salsa portion of mixed dishes.

SAUSAGES, DRIED :

PEPPERONI

25221250	PEPPERONI

SALAMI

25221500	SALAMI, NFS
25221510	SALAMI, SOFT, COOKED
25221520	SALAMI, DRY OR HARD
25221530	SALAMI, BEEF
25230840	TURKEY SALAMI
27560510	SALAMI SANDWICH W/ SPREAD

SUMMER SAUSAGE

25221810	THURINGER (INCLUDE SUMMER SAUSAGE)

OTHER SAUSAGES

25220210	BLOOD SAUSAGE
25220310	BOCKWURST
25220350	BRATWURST, COOKED
25220360	BRATWURST W/ CHEESE
25220510	CAPICOLA
25220610	CERVELAT
25220650	CHICKEN & BEEF SAUSAGE, SMOKED
25220710	CHORIZOS
25220910	HEAD CHEESE
25221110	KNOCKWURST
25221210	MORTADELLA
25221310	POLISH SAUSAGE
25221350	ITALIAN SAUSAGE
25221400	SAUSAGE (NOT COLD CUT), NFS
25221480	METTWURST
25221910	VIENNA SAUSAGE, CANNED
25221920	VIENNA SAUSAGE, CHICKEN, CANNED
25221950	PICKLED SAUSAGE

SAUSAGES, BREAKFAST[7]

25221410	PORK SAUSAGE, FRESH, BULK, PATTY OR LINK, COOKED
25221420	PORK SAUSAGE, BROWN & SERVE, COOKED
25221430	PORK SAUSAGE, COUNTRY STYLE, FRESH, COOKED
25221450	PORK SAUSAGE RICE LINKS,BROWN & SERVE, COOKED
25221460	PORK & BEEF SAUSAGE
25221470	PORK & BEEF SAUSAGE, BROWN & SERVE, COOKED
25221610	SCRAPPLE, COOKED
25221650	SMOKED LINK SAUSAGE, PORK
25221660	SMOKED LINK SAUSAGE, PORK & BEEF
25221680	SMOKED SAUSAGE, PORK
25221710	SOUSE
25221840	TURKEY BREAKFAST SAUSAGE, BULK
25221850	TURKEY SAUSAGE, SMOKED
25221860	TURKEY SAUSAGE, REDUCED FAT, BROWN & SERVE, COOKED

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[7] CSFII does not distinguish between raw and cooked sausages as well as breakfast and non-breakfast type sausages. Novigen included all sausages which may be eaten for breakfast.

25221870	TURKEY&PORK SAUSAGE,FRESH,BULK,PATTY OR LINK,COOKED
25221880	TURKEY, PORK, & BEEF SAUSAGE, REDUCED FAT, SMOKED
25221890	TURKEY, PORK, & BEEF SAUSAGE, LOWFAT, SMOKED
25220100	BEEF SAUSAGE, NFS
25220110	BEEF SAUSAGE, BROWN & SERVE, LINKS, COOKED
25220120	BEEF SAUSAGE, SMOKED, STICK (INCLUDE BEEF JERKY)
25220130	BEEF SAUSAGE, SMOKED
25220140	BEEF SAUSAGE, FRESH, BULK, PATTY OR LINK, COOKED
27120110	SAUSAGE W/ TOMATO-BASED SAUCE (MIXTURE)
27220120	SAUSAGE & RICE W/ TOMATO-BASED SAUCE (MIXTURE)
27220150	SAUSAGE & RICE W/ (MUSHROOM) SOUP (MIXTURE)
27220190	SAUSAGE & NOODLES W/ CREAM OR WHITE SAUCE (MIXTURE)
27320080	SAUSAGE, NOODLES, VEG (NO CAR/DK GRN), TOMATO SAUCE
27320090	SAUSAGE, NOODLES, VEG (W/ CAR/DK GRN), TOMATO SAUCE
27320120	SAUSAGE, POT, & VEG (INCL CAR/BROC/DK GREEN), GRAVY
27320130	SAUSAGE, POT, & VEG (NO CAR/BROC/DK GREEN), GRAVY
27420460	SAUSAGE & VEG (NO CAR/DK GRN/POT), TOMATO SAUCE
27420470	SAUSAGE & PEPPERS, NO SAUCE
27560650	SAUSAGE ON BISCUIT(INCL JIMMY DEAN SAUSAGE BISCUIT)
27560670	SAUSAGE & CHEESE ON ENGLISH MUFFIN
32105120	EGG OMELET OR SCRAMBLED EGG, W/ SAUSAGE & MUSHROOMS
32105121	EGG OMELET OR SCRAMBLED EGG, W/ SAUSAGE & CHEESE
32105122	EGG OMELET OR SCRAMBLED EGG, W/ SAUSAGE
32202030	EGG, CHEESE & SAUSAGE ON ENGLISH MUFFIN
32202050	EGG, CHEESE & SAUSAGE ON BISCUIT
32202060	EGG & SAUSAGE ON BISCUIT
58100340	BURRITO W/ EGGS, SAUSAGE, CHEESE AND VEGETABLES
58127270	CROISSANT W/ SAUSAGE & EGG
58127330	CROISSANT W/ SAUSAGE, EGG, & CHEESE
58156210	RICE W/ VIENNA SAUSAGE, P.R. (ARROZ CON SALCHICHAS)
58156310	RICE W/ SPANISH SAUSAGE, P.R.

TORTILLAS, "REFRIGERATED"[8]

58100100	BURRITO WITH BEEF, NO BEANS
58100120	BURRITO WITH BEEF, BEANS, AND CHEESE
58101240	FLAUTA WITH CHICKEN
52215000	TORTILLA, NFS
52215100	TORTILLA, CORN
52215200	TORTILLA, FLOUR (WHEAT)
52215260	TORTILLA, WHOLE WHEAT
58421080	SOPA DE TORTILLA, MEXICAN STYLE TORTILLA SOUP
58101820	MEXICAN CASSEROLE MADE WITH GROUND BEEF, BEANS, TOMATO SA
58104310	CHALUPA WITH BEANS, CHICKEN, CHEESE, LETTUCE AND TOMATO
58101940	TACO SALAD, MEATLESS,W/CHEESE, FRIED FLOUR TORTILLA
58101830	MEXICAN CASSEROLE MADE WITH GROUND BEEF, TOMATO SAUCE, CH
58100360	CHILAQUILES, TORTILLA CASSEROLE WITH SALSA, CHEESE, AND E
58101930	TACO SALAD W/ BEEF & CHEESE, FRIED FLOUR TORTILLA
58105000	FAJITA WITH CHICKEN AND VEGETABLES
58104600	CHIMICHANGA WITH BEEF AND RICE
58100350	BURRITO WITH EGGS AND CHEESE, NO BEANS

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[8] CSFII does not distinguish between tortillas sold fresh or packaged (e.g. tacos). Novigen included all tortillas and portions of tortillas in mixed dishes.

APPENDIX (CONT'D)

58104550	CHIMICHANGA WITH CHICKEN, SOUR CREAM, LETTUCE AND TOMATO,
58100330	BURRITO WITH RICE, BEANS, CHEESE, SOUR CREAM, LETTUCE, TO
58100230	BURRITO WITH CHICKEN AND CHEESE
58100610	ENCHILADA WITH CHICKEN AND BEANS, TOMATO-BASED SAUCE
58104510	CHIMICHANGA WITH BEEF, CHEESE, LETTUCE AND TOMATO
58105050	FAJITA WITH BEEF AND VEGETABLES
58100210	BURRITO WITH CHICKEN AND BEANS
58100720	ENCHILADA WITH BEANS AND CHEESE, MEATLESS
58100180	BURRITO WITH PORK AND BEANS
58100620	ENCHILADA WITH CHICKEN, BEANS, AND CHEESE, TOMATO- BASED
58100520	ENCHILADA WITH BEEF, BEANS, AND CHEESE
58100710	ENCHILADA WITH BEANS, MEATLESS
58100630	ENCHILADA WITH CHICKEN AND CHEESE, NO BEANS, TOMATO- BASE
58100320	BURRITO WITH BEANS AND CHEESE, MEATLESS
58104260	CHALUPA WITH BEANS, CHEESE, LETTUCE AND TOMATO
58100530	ENCHILADA WITH BEEF AND CHEESE, NO BEANS
58100130	BURRITO WITH BEEF AND CHEESE, NO BEANS
58101450	SOFT TACO WITH CHICKEN, CHEESE, AND LETTUCE
58104530	CHIMICHANGA WITH CHICKEN AND CHEESE
58100600	ENCHILADA WITH CHICKEN, TOMATO-BASED SAUCE
58100510	ENCHILADA WITH BEEF AND BEANS
58100800	ENCHILADA WITH CHEESE, MEATLESS, NO BEANS
58100400	ENCHILADA WITH BEEF, NO BEANS
58100150	BURRITO WITH BEEF AND POTATO, NO BEANS
58100340	BURRITO WITH EGGS, SAUSAGE, CHEESE AND VEGETABLES
58100240	BURRITO WITH CHICKEN, NFS
58100560	ENCHILADA WITH HAM AND CHEESE, NO BEANS
58104490	CHIMICHANGA, NFS
58101350	SOFT TACO WITH BEEF, CHEESE, LETTUCE, TOMATO AND SOUR CRE
58104450	CHIMICHANGA WITH BEEF AND TOMATO
58104500	CHIMICHANGA WITH BEEF, BEANS, LETTUCE AND TOMATO
58100310	BURRITO WITH BEANS, MEATLESS
58104520	CHIMICHANGA WITH BEANS AND CHEESE, MEATLESS, WITH LETTUCE
58100200	BURRITO WITH CHICKEN, NO BEANS
58100900	ENCHILADA WITH SEAFOOD, TOMATO-BASED SAUCE
58104810	TAQUITOES
58100140	BURRITO WITH BEEF, BEANS, CHEESE, AND SOUR CREAM
58100110	BURRITO WITH BEEF AND BEANS
58101400	SOFT TACO WITH BEEF, CHEESE, AND LETTUCE
58104730	QUESADILLA WITH MEAT AND CHEESE
58104710	QUESADILLA WITH CHEESE, MEATLESS
58100300	BURRITO WITH BEANS AND RICE, MEATLESS
27560380	POCHITO(FRANKFURTER/HOT DOG&BEEF CHILI IN TORTILLA)
58100220	BURRITO WITH CHICKEN, BEANS, AND CHEESE
58101200	FLAUTA, NFS
58101230	FLAUTA W/ BEEF
58105100	PUPUSA, CHEESE-FILLED
58105110	PUPUSA, MEAT-FILLED

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SOUR CREAM

12310100	SOUR CREAM (INCL W/ CHIVES)
12310200	SOUR CREAM, HALF & HALF
12310300	SOUR CREAM, REDUCED FAT
12310350	SOUR CREAM, LIGHT
12310370	SOUR CREAM, FAT FREE
12320100	SOUR CREAM, IMITATION
12320200	SOUR CREAM, FILLED, SOUR DRESSING, NONBUTTERFAT
12350000	DIP, SOUR CREAM BASE (INCLUDE BUTTERMILK-TYPE DIP)
12350020	DIP, SOUR CREAM BASE, REDUCED CALORIE
12350100	SPINACH DIP, SOUR CREAM BASE
58100140	BURRITO WITH BEEF, BEANS, CHEESE, AND SOUR CREAM
58100330	BURRITO WITH RICE, BEANS, CHEESE, SOUR CREAM, LETTUCE, TO
58101350	SOFT TACO WITH BEEF, CHEESE, LETTUCE, TOMATO AND SOUR CREAM
58104080	NACHOS WITH BEEF, BEANS, CHEESE, AND SOUR CREAM
58104090	NACHOS WITH CHEESE AND SOUR CREAM
58104550	CHIMICHANGA WITH CHICKEN, SOUR CREAM, LETTUCE AND TOMATO,

YOGURT, FROZEN

11459990	YOGURT, FROZEN, NS AS TO FLAVOR, NS TO TYPE OF MILK
11460000	YOGURT, FROZEN, NOT CHOCOLATE, TYPE OF MILK NS
11460100	YOGURT, FROZEN, CHOCOLATE, TYPE OF MILK NS
11460150	YOGURT, FROZEN, NS AS TO FLAVOR, LOWFAT MILK
11460160	YOGURT, FROZEN, CHOCOLATE, LOWFAT MILK
11460170	YOGURT, FROZEN, NOT CHOCOLATE, LOWFAT MILK
11460190	YOGURT, FROZEN, NS AS TO FLAVOR, NONFAT MILK
11460200	YOGURT, FROZEN, CHOCOLATE, NONFAT MILK
11460250	YOGURT,FROZEN,NOT CHOCOLATE,W/ SORBET/SORBET-COATED
11460300	YOGURT, FROZEN, NOT CHOCOLATE, NONFAT MILK
11460400	YOGURT,FRZ,CHOCOLATE,NONFAT MILK,W/ LOW-CAL SWEET
11460410	YOGURT,FRZ,NOT CHOC,NONFAT MILK,W/ LOW-CAL SWEET
11460420	YOGURT, FROZEN, NS AS TO FLAVOR, WHOLE MILK
11460430	YOGURT, FROZEN, CHOCOLATE, WHOLE MILK
11460440	YOGURT, FROZEN, NOT CHOCOLATE, WHOLE MILK
11461000	YOGURT, FROZEN, CHOCOLATE-COATED
11461100	YOGURT, FROZEN, CAROB-COATED
11461200	YOGURT, FROZEN, SANDWICH
11461250	YOGURT, FROZEN, CONE, CHOCOLATE
11461260	YOGURT, FROZEN, CONE, NOT CHOCOLATE
11461270	YOGURT, FROZEN, CONE, NOT CHOCOLATE, LOWFAT MILK
11461280	YOGURT, FROZ, CONE, CHOCOLATE, LOWFAT MILK

YOGURT, NON-FROZEN

11410000	YOGURT, NS AS TO TYPE OF MILK/FLAVOR
11411010	YOGURT, PLAIN, NS AS TO TYPE OF MILK
11411100	YOGURT, PLAIN, WHOLE MILK
11411200	YOGURT, PLAIN, LOWFAT MILK
11411300	YOGURT, PLAIN, NONFAT MILK
11420000	YOGURT, VANILLA, LEMON, COFFEE, NS AS TO MILK TYPE
11421000	YOGURT, VANILLA, LEMON, COFFEE, WHOLE MILK
11422000	YOGURT, VANILLA, LEMON, COFFEE, LOWFAT MILK
11423000	YOGURT, VANILLA, LEMON, COFFEE, NONFAT MILK
11424000	YOGURT, VANILLA, LEMON, COFFEE, NONFAT MILK, LOW CAL SWEET

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11425000	YOGURT, CHOCOLATE, NS AS TO TYPE OF MILK
11426000	YOGURT, CHOCOLATE, WHOLE MILK
11427000	YOGURT, CHOCOLATE, NONFAT MILK
11430000	YOGURT, FRUIT VARIETY, NS AS TO MILK TYPE
11431000	YOGURT, FRUIT VARIETY, WHOLE MILK
11432000	YOGURT, FRUIT VARIETY, LOWFAT MILK
11433000	YOGURT, FRUIT VARIETY, NONFAT MILK
11433500	YOGURT, FRUITED, NONFAT MILK, LOW CAL SWEETENER
11444000	YOGURT, FRUIT & NUTS, NS AS TO TYPE OF MILK
11445000	YOGURT, FRUIT & NUTS, LOWFAT MILK

CEREAL BARS

41435010	HIGH PROTEIN BAR, SOY BASE
41435110	HIGH PROTEIN BAR, CANDY-LIKE, SOY & MILK BASE
41435200	HIGH PROTEIN BAR, COOKIE TYPE,SOY & MILK BASE
53540000	BREAKFAST BAR, NFS
53540100	BREAKFAST BAR, CAKE-LIKE
53540200	BREAKFAST BAR, CEREAL CRUST W/ FRUIT FILLING, LOWFAT
53540250	BREAKFAST BAR, CEREAL CRUST W/ FRUIT FILLING, FAT FREE
53540500	BREAKFAST BAR, DATE, W/ YOGURT COATING
53541100	BREAKFAST BAR, DIET MEAL TYPE
53541200	MEAL REPLACEMENT BAR (INCL SLIM FAST BAR)
53542100	GRANOLA BAR W/ OATS, SUGAR, RAISINS, COCONUT
53542200	GRANOLA BAR, OATS, FRUIT, NUTS, LOWFAT
53542210	GRANOLA BAR, NONFAT
53543100	GRANOLA BAR W/ PEANUTS, OATS, SUGAR, WHEAT GERM
53544100	GRANOLA BAR, W/ NOUGAT
53544200	GRANOLA BAR, CHOCOLATE-COATED
53544210	GRANOLA BAR, W/ COCONUT, CHOCOLATE-COATED
53544220	GRANOLA BAR W/ NUTS, CHOCOLATE-COATED
53544250	GRANOLA BAR, COATED W/ NONCHOCOLATE COATING
53544300	GRANOLA BAR, HIGH FIBER, YOGURT COATING, NOT CHOC
53544400	GRANOLA BARS, W/ RICE CEREAL
53544450	POWERBAR (FORTIFIED HIGH ENERGY BAR)

SOUPS

14710100	CHEDDAR CHEESE SOUP
27111400	CHILI CON CARNE, NS AS TO BEANS
27111410	CHILI CON CARNE WITH BEANS
27111420	CHILI CON CARNE WITHOUT BEANS
27111430	CHILI CON CARNE, NS AS TO BEANS, WITH CHEESE
27111440	CHILI CON CARNE WITH BEANS AND CHEESE
27121410	CHILI CON CARNE WITH BEANS, MADE WITH PORK
27130050	LAMB OR MUTTON GOULASH
27130100	LAMB CURRY
27136100	CHILI CON CARNE WITH VENISON AND BEANS
27141500	CHILI CON CARNE WITH CHICKEN OR TURKEY AND BEANS
27212120	CHILI CON CARNE WITH BEANS AND MACARONI
27212150	BEEF GOULASH WITH NOODLES
27213150	CHILI CON CARNE WITH BEANS AND RICE
27218210	PUERTO-RICAN STYLE BEEF STEW (CARNE GUISADA CON PAPAS)
27311410	BEEF STEW WITH POTATOES AND VEGETABLES (INCLUDING CARROTS,
27311420	BEEF STEW WITH POTATOES AND VEGETABLES (EXCLUDING CARROTS,

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APPENDIX (CONT'D)

27350110	BOUILLABAISSE
27360000	STEW, NFS
27360100	BRUNSWICK STEW
27363000	GUMBO WITH RICE (NEW ORLEANS TYPE WITH SHELLFISH, PORK, AND/OR
27430400	LAMB OR MUTTON STEW WITH VEGETABLES (INCLUDING CARROTS,
27430410	LAMB OR MUTTON STEW WITH VEGETABLES (EXCLUDING CARROTS,
27430580	VEAL WITH VEGETABLES (INCLUDING CARROTS, BROCCOLI, AND/OR
28151030	SHRIMP CREOLE WITH RICE, PEPPERS (DIET FROZEN MEAL)
28310110	BEEF, BROTH, BOUILLON, OR CONSOMME
28310160	BEEF BROTH, WITH TOMATO, HOME RECIPE
28310170	BEEF BROTH, WITHOUT TOMATO, HOME RECIPE
28310210	CHILI BEEF SOUP
28310220	CHILI BEEF SOUP, CHUNKY STYLE
28310230	MEATBALL SOUP, MEXICAN STYLE (SOPA DE ALBONDIGAS)
28310320	BEEF NOODLE SOUP, PUERTO RICAN STYLE (SOPA DE CARNE Y FIDEOS)
28310330	BEEF AND RICE NOODLE SOUP, ORIENTAL STYLE (VIETNAMESE PHO BO)
28310420	BEEF AND RICE SOUP, PUERTO RICAN STYLE
28311010	PEPPERPOT (TRIPE) SOUP
28315100	BEEF VEGETABLE SOUP WITH POTATO, STEW TYPE
28315110	BEEF NOODLE SOUP, CHUNKY STYLE
28315120	BEEF VEGETABLE SOUP WITH NOODLES, STEW TYPE, CHUNKY STYLE
28315130	BEEF VEGETABLE SOUP WITH RICE, STEW TYPE, CHUNKY STYLE
28315140	BEEF VEGETABLE SOUP, MEXICAN STYLE (SOPA / CALDO DE RES)
28315150	MEAT AND HOMINY SOUP, MEXICAN STYLE (POZOLE)
28317010	BEEF STROGANOFF SOUP, CHUNKY STYLE
28320110	PORK AND RICE SOUP, STEW TYPE, CHUNKY STYLE
28320120	PORK VEGETABLE SOUP WITH NOODLES, STEW TYPE, CHUNKY STYLE
28320130	HAM, RICE, AND POTATO SOUP, PUERTO RICAN STYLE
28320140	HAM, NOODLE, AND VEGETABLE SOUP, PUERTO RICAN STYLE
28320150	PORK, VEGETABLE SOUP WITH POTATOES, STEW TYPE
28320300	PORK WITH VEGETABLE (EXCLUDING CARROTS, BROCCOLI AND/OR DARK-
28321130	BACON SOUP, CREAM OF, PREPARED WITH WATER
28330110	SCOTCH BROTH (LAMB, VEGETABLES, AND BARLEY)
28331110	LAMB, PASTA, AND VEGETABLE SOUP, PUERTO RICAN STYLE
28340110	CHICKEN, BROTH, BOUILLON, OR CONSOMME
28340120	CHICKEN BROTH, WITHOUT TOMATO, HOME RECIPE
28340210	CHICKEN RICE SOUP, PUERTO RICAN STYLE (SOPA DE POLLO CON ARROZ)
28340220	CHICKEN SOUP WITH NOODLES AND POTATOES, PUERTO RICAN STYLE
28340310	CHICKEN GUMBO SOUP
28340510	CHICKEN NOODLE SOUP, CHUNKY STYLE
28340530	CHICKEN SOUP
28340550	SWEET AND SOUR SOUP
28340580	CHICKEN SOUP WITH VEGETABLES (BROCCOLI, CARROTS, CELERY,
28340590	CHICKEN CORN SOUP, HOME RECIPE
28340610	CHICKEN OR TURKEY VEGETABLE SOUP, STEW TYPE
28340630	CHICKEN VEGETABLE SOUP WITH RICE, STEW TYPE, CHUNKY STYLE
28340640	CHICKEN VEGETABLE SOUP WITH NOODLES, STEW TYPE, CHUNKY STYLE
28340650	CHICKEN VEGETABLE SOUP WITH RICE, STEW TYPE, CHUNKY STYLE,
28340660	CHICKEN OR TURKEY VEGETABLE SOUP, HOME RECIPE
28340670	CHICKEN VEGETABLE SOUP WITH RICE, MEXICAN STYLE (SOPA / CALDO
28340690	CHICKEN VEGETABLE SOUP WITH POTATO AND CHEESE, CHUNKY STYLE
28340750	HOT AND SOUR SOUP
28345110	CHICKEN OR TURKEY SOUP, CREAM OF, NS AS TO PREPARED WITH MILK

28345120	CHICKEN OR TURKEY SOUP, CREAM OF, PREPARED WITH MILK
28345130	CHICKEN OR TURKEY SOUP, CREAM OF, PREPARED WITH WATER
28345160	CHICKEN AND MUSHROOM SOUP, CREAM OF, PREPARED WITH MILK
28345170	DUCK SOUP
28350040	FISH STOCK, HOME RECIPE
28350050	FISH CHOWDER
28350110	CRAB SOUP, NS AS TO TOMATO-BASE OR CREAM STYLE
28350210	CLAM CHOWDER, NS AS TO MANHATTAN OR NEW ENGLAND STYLE
28350220	CLAM CHOWDER, MANHATTAN
28350310	TURTLE AND VEGETABLE SOUP
28351110	FISH AND VEGETABLE SOUP, NO POTATOES (SOPA DE PESCADO)
28351120	FISH SOUP, WITH POTATOES (SOPA DE PESCADO)
28351160	CODFISH, RICE, AND VEGETABLE SOUP, PUERTO RICAN STYLE
28351170	CODFISH SOUP WITH NOODLES, PUERTO RICAN STYLE
28355110	CLAM CHOWDER, NEW ENGLAND, NS AS TO PREPARED WITH WATER OR
28355120	CLAM CHOWDER, NEW ENGLAND, PREPARED WITH MILK
28355130	CLAM CHOWDER, NEW ENGLAND, PREPARED WITH WATER
28355210	CRAB SOUP, PREPARED WITH MILK
28355250	LOBSTER BISQUE
28355260	LOBSTER GUMBO
28355310	OYSTER STEW
28355350	SALMON SOUP, CREAM STYLE
28355410	SHRIMP SOUP, CREAM OF, NS AS TO PREPARED WITH MILK OR WATER
28355420	SHRIMP SOUP, CREAM OF, PREPARED WITH MILK
28355430	SHRIMP SOUP, CREAM OF, PREPARED WITH WATER
28355440	SHRIMP GUMBO
28355450	SEAFOOD SOUP WITH POTATOES AND VEGETABLES (INCLUDING CARROTS,
28355460	SEAFOOD SOUP WITH POTATOES AND VEGETABLES (EXCLUDING
28355470	SEAFOOD SOUP WITH VEGETABLES (INCLUDING CARROTS, BROCCOLI,
28355480	SEAFOOD SOUP WITH VEGETABLES (EXCLUDING CARROTS, BROCCOLI,
32300100	EGG DROP SOUP
32301100	GARLIC EGG SOUP, PUERTO RICAN STYLE (SOPA DE AJO)
41601010	BEAN SOUP, NFS
41601020	BEAN WITH BACON OR PORK SOUP
41601030	BLACK BEAN SOUP
41601040	LIMA BEAN SOUP
41601050	SOYBEAN SOUP, MADE WITH MILK
41601060	BEAN SOUP, WITH MACARONI AND MEAT
41601070	SOYBEAN SOUP, MISO BROTH
41601080	PINTO BEAN SOUP
41601090	BEAN SOUP, WITH MACARONI
41601100	PORTUGUESE BEAN SOUP
41601110	BEAN AND HAM SOUP, CHUNKY STYLE
41601120	BEAN SOUP WITH VEGETABLES, RICE, AND PORK
41601130	BEAN SOUP, MIXED BEANS
41601140	BEAN SOUP, HOME RECIPE
41601170	BEAN AND RICE SOUP
41601180	BEAN AND HAM SOUP, HOME RECIPE
41602010	CHUNKY PEA AND HAM SOUP
41602020	GARBANZO OR CHICKPEA SOUP
41602030	SPLIT PEA AND HAM SOUP
41602050	SPLIT PEA SOUP
41603010	LENTIL SOUP

41812450	VEGETARIAN CHILI (MADE WITH MEAT SUBSTITUTE)
41812800	VEGETARIAN STEW
58155410	SOUPY RICE WITH CHICKEN, PUERTO RICAN STYLE (ASOPAO DE POLLO)
58155510	SOUPY RICE MIXTURE WITH CHICKEN AND POTATOES, PUERTO RICAN
58155810	STEWED RICE, PUERTO RICAN STYLE (ARROZ QUISADO)
58156610	PIGEON PEA ASOPAO (ASOPAO DE GANDULES)
58156710	RICE WITH STEWED BEANS, PUERTO RICAN STYLE
58400000	SOUP, NFS
58400100	NOODLE SOUP, NFS
58400200	RICE SOUP, NFS
58401010	BARLEY SOUP
58402010	BEEF NOODLE SOUP
58402020	BEEF DUMPLING SOUP
58402030	BEEF RICE SOUP
58402100	BEEF NOODLE SOUP, HOME RECIPE
58403010	CHICKEN NOODLE SOUP
58403040	CHICKEN NOODLE SOUP, HOME RECIPE
58403050	CHICKEN NOODLE SOUP, CREAM OF
58403100	NOODLE AND POTATO SOUP, PUERTO RICAN STYLE
58404010	CHICKEN RICE SOUP
58404030	CHICKEN OR TURKEY RICE SOUP, HOME RECIPE
58404100	RICE AND POTATO SOUP, PUERTO RICAN STYLE
58404500	MATZO BALL SOUP
58404510	CHICKEN SOUP WITH DUMPLINGS AND POTATOES
58404520	CHICKEN SOUP WITH DUMPLINGS
58406010	TURKEY NOODLE SOUP
58406020	TURKEY NOODLE SOUP, HOME RECIPE
58407030	SOUP, MOSTLY NOODLES
58408010	WON TON SOUP
58408500	NOODLE SOUP WITH VEGETABLES, ORIENTAL STYLE
58409000	NOODLE SOUP, WITH FISH BALL, SHRIMP, AND DARK GREEN LEAFY
58421010	SOPA SECA DE FIDEO, MEXICAN STYLE, MADE WITH DRY NOODLES
58421020	SOPA DE FIDEO AGUADA, MEXICAN STYLE NOODLE SOUP
58421080	SOPA DE TORTILLA, MEXICAN STYLE TORTILLA SOUP
58450300	NOODLE SOUP, MADE WITH MILK
71106050	POTATO FROM PUERTO RICAN BEEF STEW, WITH GRAVY
71703000	STEWED POTATOES, MEXICAN STYLE (PAPAS GUISADAS)
71703040	STEWED POTATOES WITH TOMATOES, MEXICAN STYLE (PAPAS GUISADAS
71704000	STEWED POTATOES WITH TOMATOES
71801000	POTATO SOUP, NS AS TO MADE WITH MILK OR WATER
71801010	POTATO SOUP, PREPARED WITH MILK
71801020	POTATO SOUP, PREPARED WITH WATER
71801100	POTATO AND CHEESE SOUP
71802010	MACARONI AND POTATO SOUP
71803010	POTATO CHOWDER
71805010	VICHYSSOISE SOUP
72302000	BROCCOLI SOUP
72302100	BROCCOLI CHEESE SOUP, PREPARED WITH MILK
72305000	ESCAROLE SOUP
72306000	WATERCRESS BROTH WITH SHRIMP
72307000	SPINACH SOUP
72308000	DARK-GREEN LEAFY VEGETABLE SOUP WITH MEAT, ORIENTAL STYLE
72308500	DARK-GREEN LEAFY VEGETABLE SOUP, MEATLESS, ORIENTAL STYLE

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73501000	CARROT SOUP, CREAM OF, PREPARED WITH MILK
73501010	CARROT WITH RICE SOUP, CREAM OF, PREPARED WITH MILK
75317000	VEGETABLES, STEW TYPE (INCLUDING POTATOES, CARROTS, ONIONS,
75317010	VEGETABLES, STEW TYPE (INCLUDING POTATOES, CARROTS, ONIONS,
75317020	VEGETABLES, STEW TYPE (INCLUDING POTATOES, CARROTS, ONIONS,
75600150	SOUP, CREAM OF, NFS
75601000	ASPARAGUS SOUP, CREAM OF, NS AS TO MADE WITH MILK OR WATER
75601010	ASPARAGUS SOUP, CREAM OF, PREPARED WITH MILK
75601020	ASPARAGUS SOUP, CREAM OF, PREPARED WITH WATER
75601100	BEET SOUP (BORSCHT)
75601200	CABBAGE SOUP
75601210	CABBAGE WITH MEAT SOUP
75602010	CAULIFLOWER SOUP, CREAM OF, PREPARED WITH MILK
75603000	CELERY SOUP, CREAM OF, NS AS TO MADE WITH MILK OR WATER
75603010	CELERY SOUP, CREAM OF, PREPARED WITH MILK
75603020	CELERY SOUP, CREAM OF, PREPARED WITH WATER
75604010	CORN SOUP, CREAM OF, PREPARED WITH MILK
75604020	CORN SOUP, CREAM OF, PREPARED WITH WATER
75604510	CUCUMBER SOUP, CREAM OF, PREPARED WITH MILK
75604600	GAZPACHO
75605010	LEEK SOUP, CREAM OF, PREPARED WITH MILK
75607000	MUSHROOM SOUP, NFS
75607010	MUSHROOM SOUP, CREAM OF, PREPARED WITH MILK
75607020	MUSHROOM SOUP, CREAM OF, PREPARED WITH WATER
75607040	MUSHROOM SOUP, WITH MEAT BROTH, PREPARED WITH WATER
75607050	MUSHROOM SOUP, CREAM OF, PREPARED WITH WATER, LOW SODIUM
75607060	MUSHROOM SOUP, CREAM OF, NS AS TO MADE WITH MILK OR WATER
75607070	MUSHROOM SOUP, CREAM OF, PREPARED WITH LOWFAT MILK
75607080	MUSHROOM WITH CHICKEN SOUP, CREAM OF, PREPARED WITH MILK
75608010	ONION SOUP, CREAM OF, PREPARED WITH MILK
75608100	ONION SOUP, FRENCH
75609000	PEA SOUP, NFS
75609010	PEA SOUP, PREPARED WITH MILK
75609020	PEA SOUP, PREPARED WITH WATER
75609060	PEA SOUP, PREPARED WITH LOWFAT MILK
75611010	VEGETABLE SOUP, CREAM OF, PREPARED WITH MILK
75612010	ZUCCHINI SOUP, CREAM OF, PREPARED WITH MILK
75647000	SEAWEED SOUP
75649010	VEGETABLE SOUP, PREPARED WITH WATER OR READY-TO-SERVE
75649110	VEGETABLE SOUP, HOME RECIPE
75649150	VEGETABLE NOODLE SOUP, HOME RECIPE
75651000	MINESTRONE SOUP, HOME RECIPE
75651010	VEGETABLE BEAN SOUP, PREPARED WITH WATER OR READY-TO-SERVE
75651020	VEGETABLE BEEF SOUP, PREPARED WITH WATER
75651030	VEGETABLE BEEF NOODLE SOUP, PREPARED WITH WATER
75651040	VEGETABLE NOODLE SOUP, PREPARED WITH WATER
75651050	VEGETABLE CHICKEN OR TURKEY SOUP, PREPARED WITH WATER OR
75651070	VEGETABLE RICE SOUP, PREPARED WITH WATER
75651080	VEGETABLE BEEF SOUP WITH RICE, PREPARED WITH WATER OR READY-
75651110	VEGETABLE CHICKEN RICE SOUP, PREPARED WITH WATER OR READY-TO-
75651120	VEGETABLE CHICKEN NOODLE SOUP, PREPARED WITH WATER OR READY-
75651140	VEGETABLE SOUP WITH CHICKEN BROTH, MEXICAN STYLE (SOPA
75652010	VEGETABLE BEEF SOUP, HOME RECIPE

75652040	VEGETABLE BEEF SOUP WITH NOODLES OR PASTA, HOME RECIPE
75652050	VEGETABLE BEEF SOUP WITH RICE, HOME RECIPE
75654010	VEGETARIAN VEGETABLE SOUP, PREPARED WITH WATER
75654020	VEGETARIAN VEGETABLE SOUP, UNDILUTED
75656020	VEGETABLE SOUP, CHUNKY STYLE
75656040	VEGETABLE SOUP, WITH PASTA, CHUNKY STYLE
75656060	VEGETABLE BEEF SOUP, CHUNKY STYLE
75657000	VEGETABLE BROTH, BOUILLON
76801000	VEGETABLE SOUP, CREAM OF, BABY FOOD
77513010	SPANISH STEW, PUERTO RICAN STYLE (COCIDO ESPANOL)
77563010	PUERTO RICAN STEW (SANCOCHO)

HASH BROWN POTATOES

35001000	SCRAMBLED EGGS, SAUSAGE, HASH BROWN POT (FROZ MEAL)
35002000	SCRAMBLED EGGS, BACON, HOME FRIED POT (FRZ MEAL)
71405000	WHITE POTATO, HASH BROWN
71405020	WHITE POTATO, HASH BROWN, FROM FROZEN
71405100	WHITE POTATO, HASH BROWN W/ CHEESE
71701000	POTATO PANCAKE

SCONES AND MUFFINS

52105100	SCONES
52105110	SCONES, WHOLE WHEAT
52105200	SCONE, WITH FRUIT
52301000	MUFFIN, NFS
52302010	MUFFIN, FRUIT & OR NUTS
52302100	MUFFIN, FRUIT, FAT FREE, CHOL FREE
52302500	MUFFIN, CHOCOLATE CHIP
52302600	MUFFIN, CHOCOLATE
52303010	MUFFIN, WHOLE WHEAT
52303500	MUFFIN, WHEAT
52303550	MUFFIN, BUCKWHEAT
52304010	MUFFIN, WHEAT BRAN (INCLUDE W/ RAISINS & NUTS)
52304020	MUFFIN, WHEAT BRAN, TOASTED (INCL W/ RAISINS & NUTS)
52304040	MUFFIN,BRAN,W/ FRUIT, LOWFAT
52304060	MUFFIN, BRAN W/ FRUIT, NO FAT, NO CHOLESTEROL
52304100	MUFFIN, OATMEAL
52304150	MUFFIN, OAT BRAN
52304200	MUFFIN, OAT BRAN WITH FRUIT AND/OR NUTS
52306010	MUFFIN, PLAIN
52306100	MUFFIN, PLAIN, NO WHEAT, SUGAR-FREE
52306300	MUFFIN, CHEESE
52306500	MUFFIN, PUMPKIN, W/ RAISINS
52306550	MUFFIN, ZUCCHINI
52306700	MUFFIN, CARROT (INCL W/ RAISINS/NUTS)
52307020	MUFFIN, MULTIGRAIN, W/ NUTS
52307120	MUFFIN, MULTIGRAIN, WITH FRUIT
52308010	MATZO FRITTERS
52311010	POPOVER
52320100	TOASTER MUFFIN, FRUIT, UNTOASTED
52320110	TOASTER MUFFIN, FRUIT, TOASTED

DELI SALADS

27351060	SHRIMP & PASTA GARDEN SALAD W/ TOM/CAR, NO DRESSING
27420020	HAM OR PORK SALAD
27446200	CHICKEN OR TURKEY SALAD
27446220	CHICKEN SALAD W/ EGG
27446300	CHICKEN GARDEN SALAD W/ TOMATO/CARROT, NO DRESSING
27446310	CHICKEN GARDEN SALAD W/VEG, NO CAR/TOM, NO DRESSING
27446350	ORIENTAL CHICKEN GARDEN SALAD, NO DRESSING
27450010	CRAB SALAD
27450020	LOBSTER SALAD
27450030	SALMON SALAD
27450040	SHRIMP CHOW MEIN OR CHOP SUEY, NO NOODLES
27450060	TUNA SALAD
27450070	SHRIMP SALAD
27450080	SEAFOOD SALAD
27450090	TUNA SALAD W/ CHEESE
27450100	TUNA SALAD W/ EGG
27450110	SHRIMP GARDEN SALAD W/ TOMATO/CARROT, NO DRESSING
27450120	SHRIMP GARDEN SALAD (NO TOMATO/CARROT, NO DRESSING)
27450130	CRAB SALAD MADE W/ IMITATION CRAB
27450420	SHRIMP & VEG (NO CARROT/DK GREEN, NO POT),SOY SAUCE
27460490	JULIENNE SALAD (MEAT, CHEESE, EGG, VEG) NO DRESSING
27460510	ANTIPASTO W/ HAM, FISH, CHEESE, VEGETABLES
27520340	HAM SALAD SANDWICH
27540120	CHICKEN SALAD OR CHICKEN SPREAD SANDWICH
27540320	TURKEY SALAD SANDWICH
27550710	TUNA SALAD SANDWICH W/ LETTUCE
27550720	TUNA SALAD SANDWICH
27550750	TUNA SALAD SUB, ON ROLL, W/ LETTUCE
32103000	EGG SALAD
32203010	EGG SALAD SANDWICH
41203020	KIDNEY BEAN SALAD
58101940	TACO OR TOSTADA SALAD, MEATLESS, WITH CHEESE, FRIED FLOUR TORTILLA
58148110	MACARONI SALAD
58148120	MACARONI SALAD W/ EGG
58148130	MACARONI SALAD W/ TUNA
58148140	MACARONI SALAD W/ CRAB MEAT
58148150	MACARONI SALAD W/ SHRIMP
58148160	MACARONI SALAD W/ TUNA & EGG
58148170	MACARONI SALAD W/ CHICKEN
58148180	MACARONI SALAD W/ CHEESE (INCL MADE W/ CELERY, CUCU
58148500	PASTA SALAD (MACARONI OR NOODLES, VEG, DRESSING)
58148550	PASTA SALAD W/ MEAT (MACARONI, VEG, MEAT, DRESSING)
63401010	APPLE SALAD WITH DRESSING
63401020	APPLE AND CABBAGE SALAD WITH DRESSING
63402950	FRUIT SALAD (EXCLUDING CITRUS FRUITS) WITH SALAD DRESSING OR MAYONNAISE
63402960	FRUIT SALAD (EXCLUDING CITRUS FRUITS) WITH CREAM
63402970	FRUIT SALAD (EXCLUDING CITRUS FRUITS) WITH CREAM SUBSTITUTE
63402980	FRUIT SALAD (EXCLUDING CITRUS FRUITS) WITH MARSHMALLOWS
63403000	FRUIT SALAD (EXCLUDING CITRUS FRUITS) WITH PUDDING
63403010	FRUIT SALAD (INCLUDING CITRUS FRUITS) WITH SALAD DRESSING OR MAYONNAISE
63403020	FRUIT SALAD (INCLUDING CITRUS FRUIT) WITH CREAM

APPENDIX (CONT'D)

63403030	FRUIT SALAD (INCLUDING CITRUS FRUITS) WITH CREAM SUBSTITUTE
63403040	FRUIT SALAD (INCLUDING CITRUS FRUITS) WITH MARSHMALLOWS
63403100	FRUIT DESSERT WITH CREAM AND/OR PUDDING AND NUTS
63409020	CHUTNEY
63411010	CRANBERRY SALAD, CONGEALED
63412010	PEAR SALAD WITH DRESSING
63413020	PINEAPPLE SALAD WITH CREAM CHEESE
71601010	POTATO SALAD WITH EGG
71602010	POTATO SALAD, GERMAN STYLE
71603010	POTATO SALAD
75140500	BROCCOLI SALAD WITH CAULIFLOWER, CHEESE, BACON BITS, AND DRESSING
75144100	LETTUCE, WILTED, WITH BACON DRESSING

[Code of Federal Regulations]
[Title 21, Volume 2]
[Revised as of April 1, 2002]
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[Page 357-358]

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

PART 133--CHEESES AND RELATED CHEESE PRODUCTS--Table of Contents

Subpart B--Requirements for Specific Standardized Cheese and Related Products

Sec. 133.**195** Swiss and emmentaler cheese.

(a) Description. (1) Swiss cheese, emmentaler cheese, is the food prepared by the procedure set forth in paragraph (a)(3) of this section, or by any other procedure which produces a finished cheese having the same physical and chemical properties. It has holes or eyes developed throughout the cheese. The minimum milkfat content is 43 percent by weight of the solids and the maximum moisture content is 41 percent by weight, as determined by the methods described in Sec. 133.5. The dairy ingredients used may be pasteurized. Swiss cheese is at least 60 days old.

(2) If pasteurized dairy ingredients are used, the phenol equivalent value of 0.25 gram of swiss cheese is not more than 3 micrograms as determined by the method described in Sec. 133.5.

(3) One or more of the dairy ingredients specified in paragraph (b)(1) of this section may be bleached, warmed, or treated with hydrogen peroxide/catalase, and is subjected to the action of lactic acid-producing and propionic acid-producing bacterial cultures. One or more of the clotting enzymes specified in paragraph (b)(2) of this section is added to set the dairy ingredients to a semisolid mass. The mass is cut into particles similar in size to wheat kernels. For about 30 minutes the particles are alternately stirred and allowed to settle. The temperature is raised to about 126 deg.F. Stirring is continued until the curd becomes firm. The acidity of the whey at this point, calculated as lactic acid, does not exceed 0.13 percent. The curd is transferred to hoops or forms and pressed until the desired shape and firmness are obtained. The cheese is then salted by immersing it in a saturated salt solution for about 3 days. It is then held at a temperature of about 50 deg. to 60 deg.F. for a period of 5 to 10 days, after which it is held at a temperature of about 75 deg.F. until it is approximately 30 days old, or until the so-called eyes form. Salt, or a solution of salt in water, is

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added to the surface of the cheese at some time during the curing process. The cheese is then stored at a lower temperature for further curing. One or more of the optional ingredients specified in paragraph (b)(3) of this section may be added during the procedure.

(b) Optional ingredients. The following safe and suitable ingredients may be used:

(1) Dairy ingredients. Milk, nonfat milk, or cream, as defined in Sec. 133.3, used alone or in combination.

(2) Clotting enzymes. Rennet and/or other clotting enzymes of animal, plant, or microbial origin.

(3) Other optional ingredients. (i) Coloring.

(ii) Calcium chloride in an amount not more than 0.02 percent (calculated as anhydrous calcium chloride) by weight of the dairy ingredients, used as a coagulation aid.

(iii) Enzymes of animal, plant, or microbial origin, used in curing or flavor development.

(iv) Antimycotic agents, the cumulative levels of which shall not exceed good manufacturing practice, may be added to the surface of the cheese.

(v) Benzoyl peroxide or a mixture of benzoyl peroxide with potassium alum, calcium sulfate, and magnesium carbonate used to bleach the dairy ingredients. The weight of the benzoyl peroxide is not more than 0.002

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percent of the weight of the milk being bleached, and the weight of the potassium alum, calcium sulfate, and magnesium carbonate, singly or combined, is not more than six times the weight of the benzoyl peroxide used. If milk is bleached in this manner, vitamin A is added to the curd in such quantity as to compensate for the vitamin A or its precursors destroyed in the bleaching process, and artificial coloring is not used.

(vi) Hydrogen peroxide, followed by a sufficient quantity of catalase preparation to eliminate the hydrogen peroxide. The weight of the hydrogen peroxide shall not exceed 0.05 percent of the weight of the milk and the weight of the catalase shall not exceed 20 parts per million of the weight of the milk treated.

(c) Nomenclature. The name of the food is ``swiss cheese'', or alternatively, ``emmentaler cheese''.

(d) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

(1) Enzymes of animal, plant, or microbial origin may be declared as ``enzymes''; and

(2) The dairy ingredients may be declared, in descending order of predominance, by the use of the terms ``milkfat and nonfat milk'' or ``nonfat milk and milkfat'', as appropriate.

[48 FR 2746, Jan. 21, 1983; 48 FR 11426, Mar. 18, 1983, as amended at 55 FR 6795, Feb. 27, 1990; 58 FR 2895, Jan. 6, 1993]

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington DC 20204

MAR 9 1983

George Weber, Ph.D.
Vice President
Wessman Foods, Inc.
12890 S.W. Hackemore Court
Beaverton, OR 97005

Dear Dr. Weber:

This letter is being written as a follow-up to my telephone conversation of March 7, 1983 with Mr. Dale Madden, President of Wessman Foods, Inc., concerning your firm's product "Microgard".

We have reviewed the material concerning "Microgard" (a cultured skim milk product) which you supplied us in your letter of January 21, 1983 and our meeting of February 7, 1983. Because we were not provided with the identity of the specific microbal organism(s) used in culturing the skim milk, we are unable to comment with finality. However, if the culturing organisms used to produce "Microgard" are among those traditionally used for culturing dairy products, and the product is suitable for its intended use, we would not object to the use of the product under the Cottage Cheese standard (21 CFR 133.128).

If you have any additional questions on this matter please feel free to contact us.

Sincerely yours,

Thomas D. Gardine
Assistant to the Director
Division of Regulatory Guidance
Bureau of Foods

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington DC 20204

APR 26 1983

George Weber, Ph.D.
Vice President
Wessman Foods, Inc.
12890 S.W. Hackemore Court
Beaverton, OR 97005

Dear Dr. Weber:

This responds to your letter of March 31, 1983 regarding the labeling of Cottage Cheese to which "Microgard" (a culture skim milk product) is added.

As was stated in my letter to you, of March 9, 1983, if "Microgard" is made by culturing pasteurized skim milk and the culturing organisms used to produce "Microgard" are safe and suitable organisms and among those traditionally used for culturing dairy product, then we would not object to the use of "Microgard" as an ingredient in the creaming mixture as provided for under the Cottage Cheese standard (21 CFR 133.128).

Similarly, if "Microgard" is made by culturing pasteurized skim milk, and the culturing organisms used are among those traditionally used for culturing dairy products, we would not object to the "Microgard" being designated as "cultured skim milk" on the label the Cottage Cheese in which it is used.

Sincerely yours,

Thomas D. Gardine
Assistant to the Director
Division of Regulatory Guidance
Bureau of Foods

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WESMAN FOODS INC.

PORTLAND, OREGON

January 21, 1983

CONFIDENTIAL INFORMATION

Thomas D. Gardine
Assistant to the Director
Division of Regulatory Guidance
Bureau of Foods
Food and Drug Administration
200 C Street, S.W.
Washington, D.C. 20204

Dear Mr. Gardine:

Thank you for your letter of January 4, 1983. It appears from your inquiries that we will be able to resolve the use of Microgard quite quickly.

Wesman Foods, Inc., has had a contractual research agreement with Oregon State University for the last few years. During this time, efforts have been directed toward the development of flavor "stabilizers", or more specifically, items that allow for the flavor present at packaging of cultured dairy products to remain for longer periods of time. In effect, we are trying to extend the shelf-life of certain cultured dairy products. Microgard is the result of such efforts.

I think that the best way to explain our product is to answer your specific questions. It is not a complex product. Consequently, we have treated it in an extremely confidential fashion.

1. Strains of propionibacteria obtained from the American Type Culture Collection and common as the "eye formers" in Swiss cheese are used in producing Microgard.

2. The composition of the substrate or medium in which the bacteria are grown is pasteurized skim milk.

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3. As far as we can determine, two major by-products are produced as a result of incubation, these are propionic and acetic acids. Both of these components, propionic acid alone and the combination of propionic and acetic acids, have been shown to have antimycotic action (Reynolds and Carpenter, J. of Animal Science, 38; 515-519, Anderson, Food Industries, 72, 1945). There has also been some indication in the literature of select strains of propionibacteria producing in milk, variable amounts of diacetyl (Lee, et al, Canadian J. of Microbiology, 16; 1231-1242, 1970).

4-5. H.P. Hood has apparently indicated to you that Microgard has a strong flavor enhancing effect. This is not true. On the contrary, Microgard, when added to cottage cheese, for example, is capable of maintaining, for a limited time, the flavor levels present at packaging. Microgard will not obscure unsanitary conditions that might be present at packaging. Our data indicates that the quality of the product can only be maintained, not improved. We have found the effect of Microgard to be bacteriostatic rather than bacteriocidal. We are not adding any flavoring agents, rather we are carefully pre-culturing the cheese dressing in a fashion virtually identical to, and approved for, Strep. diacetylactis.

The following results support our conclusions. Table 1 shows data obtained from gas chromatography analysis of skim milk grown proprionibacteria incubated for various times.

Table 1. mg/l (ppm)

Incubation Time	Acetic Acid	Proprionic Acid
24 hours	310	106
48 hours	87	35
72 hours	582	713
96 hours	778	1064

We find antimycotic activity to be more effective with cultures grown for the longer periods of time.

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In a similar fashion, we have analyzed the effect of Microgard on cell metabolism by measuring relative microbial activity and percent respiration using 14C-glucose uptake.

In this experiment, psychrophilic organisms, obtained as contaminants in commercial cheeses, were incubated with Microgard at either 0.1% or 1.0% for 10 minutes. This was followed by incubation for 60 minutes in the presence of 14C-glucose. Samples were analyzed for both released $14CO_2$ and 14C incorporated into cellular material.

Table 2. DPM

	CO_2	Cell	Total	% Respir.
Control (no Microgard)	48,100	51,592	99,692	48%
Microgard				
0.1%	3,367	566	3,933	86%
1.0%	1,871	193	2,064	91%

These results indicate that after exposure to Microgard, the cell's activity is shifted to one of almost complete maintenance, i.e., approximately 90% of the activity is in the form of respiration, while incorporating only 4% of the available glucose.

These results become more significant when examining cell viability. In conditions virtually identical to those described above, exposure of cells to Microgard (up to 10%) resulted in the cell's retaining their full ability to grow.

The total effect, as seen here, is to slow down the growth of spoilage organisms, not, as might be implied, to destroy them.

Very truly yours,

George H. Weber, Ph.D.
Vice President of Wesman Foods, Inc.

GHW/smn

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington DC 20204

JAN 4 1983

George Weber
Vice President
Wessman Foods
12890 S. W. Hackamore Court
Beaverton, OR 97005

Dear Mr. Weber:

This letter is written as a follow-up to our telephone conversation of December 28, 1982 regarding the experimental microbial inhibitor you have been supplying to H. P. Hood, Inc. Charleston, Massachusetts.

As you are apparently aware, we have had extensive contacts with representatives of H. P. Hood, Inc., attempting to determine the identity of this experimental microbial inhibitor and to determine its exact effect on the cottage cheese.

We have been informed by H. P. Hood that their contractual arrangement with Wessman Foods is such that they can not divulge information concerning this product. You confirmed this during our telephone conversation. We truly appreciate the apparently cooperative attitude which you assumed during our telephone conversation and hope that, together, we will be able to quickly resolve this matter.

We request that you supply us with all data you have which will help us to understand and evaluate this unknown microbial inhibitor. We particularly need to know the following information.

1. The identity of the specific bacteria used in producing this experimental product.

2. The composition of the substrate in which the bacteria grow prior to drying. For example, is the substrate milk derived?

3. What chemical or chemicals are produced through the life-cycle of the bacteria, or by any other process, that could have an inhibitory effect on the subsequent growth of molds (antimycotic action).

4. There has been some indication from H. P. Hood, Inc., that the unknown product also has a strong flavor enhancing effect. Is this true?

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5. If a flavor enhancing effect is achieved, is it because of a flavor component being produced during the life-cycle of the bacteria? What is this flavor component? If not through the life-cycle of the bacteria how is any flavor enhancing effect achieved.

As we discussed during our telephone conversation, because this is a developmental product, we would treat all information which is supplied to us at this time as confidential commercial and/or trade-secret information. As such it would not be available for public disclosure under the Freedom of Information Act and FDA's implementing regulations. However, once the product is marketed only that information considered to be trade secrets and commercial or financial information would be exempt from disclosure under the Freedom of Information Act. This could include manufacturing methods or procedures, quality control procedures, formulas and financial information.

Sincerely yours,

Thomas D. Gardine
Assistant to the Director
Division of Regulatory Guidance
Bureau of Foods

United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

21 AUG 1987

Mr. George H. Weber, Vice-President
Wesman Foods, Inc.
15240 NW Greenbrier Parkway
Beaverton, OR 97006

Dear Mr. Weber:

This is in reference to your letter of August 4, 1987, and to confirm our phone conversation on August 18, 1987.

As you requested, MICROGARD may be used in meat and poultry food products that are permitted to contain dairy products. Its use should be indicated in the ingredients statement as "cultured skim milk." However, no claims may be made on the label regarding shelflife extension or delayed spoilage unless data can be provided to demonstrate that these claims are accurate for the meat or poultry food product in which MICROGARD is used.

I hope this information is of assistance to you. If you have any questions, please feel free to call our office at (202) 447-7503.

Sincerely,

Jennifer L. Anderson
Food Technologist
Standards Branch
Standards and Labeling Division
Technical Service

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Health and Welfare Canada
Santé et Bien-être social Canada

Health Protection Branch
Direction générale de la protection de la santé

Bureau of Chemical Safety
Food Directorate
4th Floor East
Banting Building
Ottawa, Ontario
K1A 0L2

January 5, 1994

Dr. George H. Weber
Vice President
Wesman Foods, Inc.
15240 N.W. Greenbrier Parkway
Beaverton, Oregon 97006
U.S.A.

Dear Dr. Weber:

This is in response to your letters of August 25, 1992 and August 16, 1993 concerning the proposed use of your MicroGARD products (cultured skim milk and cultured dextrose) in a number of dairy and non-dairy foods.

We have now completed our review of this matter and, based on the data submitted, we would see no reason to object to the addition of MicroGARD, at the proposed levels of use, to food products which are not standardized under the Canadian Food and Drug Regulations. Among the foods listed in your documents, yogurt, dips, salsa, soup base, pasta sauces, pizza sauce, bagels, fresh pasta and shortcakes are some examples of unstandardized foods.

On the other hand, examples of standardized foods are cheeses, sour cream, butter, certain salad dressings, certain breads, pepperoni, sausage and snack meats. In connection with the proposed use of MicroGARD in these and other standardized foods, appropriate amendments to the applicable standards would be required before the preparations could be used in such foods. Should you wish to pursue proposals for the use of MicroGARD in specified standardized foods, please contact:

Dr. Frank Welsh
Bureau of Food Regulatory, International
& Interagency Affairs
Health Protection Branch
Health Canada
Room 200, Health Protection Building
Tunney's Pasture
Ottawa, Ontario K1A 0L2

Canada

Furthermore, before marketing your products in Canada, we would strongly suggest that all claims and labels of your preparations be reviewed by the Consumer Products Branch, Agriculture and Agri-Food Canada. Ms. Lee-Spiegelberg, at the address below, will be able to assist you in these matters.

Ms. Sue Lee-Spiegelberg
Food Programs
Consumer Products Branch
Agriculture and Agri-Food Canada
Place du Portage, Phase I
50 Victoria Street
Hull, Quebec K1A 0C9

The above opinion on the acceptability of the MicroGARD products per se is based on the data submitted in your letters of August 25, 1992 and August 16, 1993. Should you contemplate any change in your formulations, we may wish to reassess our position on this matter.

We trust that this is a satisfactory response to your requests.

Yours truly,

Diana Chard
Additives & Contaminants Section
Chemical Evaluation Division

cc Dr. Frank Welsh, BFRIIA
Mr. Paul Mayers, Microbial Evaluation Division
Ms. Sue Lee-Spiegelberg, AAFC

Pages 000096 - 000107 have been removed in accordance with copyright laws. Please see appended bibliography list of the references that have been removed from this request.

Pages 000108 - 000115 have been removed in accordance with copyright laws. Please see appended bibliography list of the references that have been removed from this request.

Pages 000116 - 000121 have been removed in accordance with copyright laws. Please see appended bibliography list of the references that have been removed from this request.

End Submission

Reference List for Industry Submission, GRN 000128

Pages	*Author*	*Title*	*Publish Date*	*Publisher*	*BIB_Info*
000096 - 000107	Mogensen, G.; Salminen, S.; OBrien, J.; Ouwehand, A.; Holzapfel, W.; Shortt, C.; Fonden, R.; Miller, G. D.; Donohue, D.; Playne, M.; Crittenden, R.; Bianchi Salvadori, B.; Zink, R.	Health benefits and safety evaluation of certain food components: Inventory of Microorganisms with a Documented History of Use in Food	2002	Journal of the International Dairy Federation	Number 377, pgs 77-86
000108 - 000115	Cummins, C.S.; Johnson, John L.	Irregular Nonsporing Gram Positive Rods: List of species of the genus Rothia: Genus I. Propionibacterium Orla-Jensen 1909 337 AL	NA	NA	pgs1346 -1353
000116 - 000121	Buard, A.; Carlton, B.D.; Floch, F.; Simon, G.S.	Subchronic toxicity, mutagenicity and allergenicity studies of a cultured dextrose food product	2003	Food and Chemical Toxicology	Volume 41, pgs 689-694

NA- Not applicable

AM

1850 M Street, Suite 400, Washington, D.C., N.W.
Telecopier: (202) 466-5777
Telephone: (202) 466-4500
Email: rsindt@krooth.com

Robert H. Sindt
Attorney at Law

FAX

To:	Dr. Negash Belay, OPA/CFSAN/FDA	**From:**	Robert H. Sindt
Fax:	202-418-3131	**Pages:**	4
Phone:		**Date:**	09/05/03
Re:	GRN 128—Reply to Email Comments	**CC:**	

☐ **Urgent** ☐ **For Review** ☐ **Please Comment** ☐ **Please Reply** ☐ **Please Recycle**

• Comments: The following letter replies, on behalf of Rhodia, to your August 12 email regarding GRN 128. If you have further questions, please contact me. Thank you.

ROBERT H. SINDT
ATTORNEY AT LAW

1850 M Street, N.W., Suite 400
Washington, D.C. 20036
Phone 202-466-4500 • Fax 202-466-5777 • E-mail rsindt@krooth.com

September 3, 2003

Dr. Negash Belay
Consumer Safety Officer
Office of Premarket Approval
Center for Food Safery and Applied Nutrition
Food and Drug Administration
200 C Street, SW
Washington, DC 20204

Re: GRAS Notice 128—Response to August 12, 2003 Comments

Dear Dr. Belay:

On behalf of my client, Rhodia Inc., this will provide Rhodia's replies to your above referenced email seeking comments on GRAS Notice 128. Your comments/questions and Rhodia's replies follow:

- On page 4 the notice states that the culture is maintained as frozen 1 ml vials at 80°C. The temperature should be -80°C and we assume that this was a typographical error.
  Answer: Yes, it is a typographical error and the temperature should be -80°C.

- Concerning the fermentation process, the notice states on page 5 that the pH is neutralized at the fermentation endpoint. However, on page 24, the notice also states that the pH is adjusted to 6 for this same stage of the fermentation process. Please clarify this inconsistency.
  Answer: The use of the term "neutralized" was not meant to equate to pH neutrality, but more precisely to the fact that at the fermentation endpoint, there is standardization to pH 6, if necessary.

- The notified substance is to be used in a number of foods, including raw breakfast sausage. We are concerned the use in raw breakfast sausages may inadvertently create a botulism hazard. We note that the substance is not effective against Gram positive bacteria (statement on pgs. 5-6 of the notice), which would include *Clostridium botulinum*.
  Answer: Rhodia Inc. and a major food processor have recently conducted extensive trials on the use of cultured dextrose in raw sausage. Under normal conditions, raw sausage typically spoils readily from the naturally occurring gram negative and lactic bacteria found in the raw meat. The use of cultured dextrose can only postpone the outgrowth of select gram negative spoilage organisms, but

does not prevent spoilage due to the gram positive lactic bacteria present in raw sausage. Data from our many shelf life experiments does indicate that gram positive lactic bacteria occur at very high levels in raw sausage, and these bacteria consistently spoil product that has not been spoiled by gram negative bacteria.

When viewed from the perspective of competitive exclusion of pathogens, these non-pathogenic gram positive lactic bacteria, without competition from the gram negative bacteria controlled by the notified substance(s), can exhibit an inhibitory effect (via microbial competitive exclusion) on the very low, if at all, number of potential pathogens such as slow growing *Clostridium botulinum* growth. The net effect is an extension of effective shelf life while maintaining the natural inhibition of *C. botulinum* growth.

Consequently, it is Rhodia's opinion that the risk of *C. botulimum* in this application appears negligible. Indeed, years of use of MicroGARD products in various foods has not created any known botulism hazard(s).

- On page 8 the notice states that the independent expert panels' reports are dated March, 1966 and October, 2000. However, the two expert panel reports that are included in the notice are dated March, 1996 and July, 2002. Please clarify this inconsistency.
  Answer: The page 8 reference to October 2000 is an inadvertent error. It should have stated July 2002.

- On page 11, the notice refers to "*freudenreichii*" as genus rather than species.
  Answer: This is an inadvertent error. The reference should have been to species rather than to genus.

- The information on page 67 of the notice, a 1983 Wesman Foods letter, is identified as confidential information. Please clarify if Rhodia still considers this information to be confidential.
  Answer: The letter was marked confidential by Wesman Foods, a concern that Rhodia acquired in 1995. Rhodia does not now consider it to be confidential and asks that you disregard the confidentiality marking on the letter.

- The notifier specifies that either skim milk solids or dextrose is added to "standardize" the Microgard ingredient. What percentage (or range) of milk solids or dextrose is the ingredient standardized to?
  Answer: The amount of solids needed for standardizing will necessarily vary depending on the fermentation yield, but the range of added solids is typically 50-65% of total solids in the dried product.

Additionally, it is noted that your email and FDA's GRAS Notice website refer to Rhodia's notice as "GRN 128 - Skim milk or dextrose cultured with *Propionibacterium freudenreichii subsp. shermanii* (ATCC No. 9616)", specifying the specific isolate, ATCC No. 9616. While Rhodia clearly asserts that skim milk or destrose cultured with *P.*

freudenreichii subsp.shermanii (ATCC No. 9616) is GRAS, it was not Rhodia's intent to establish that only skim milk or dextrose cultured with the particular isolate, ATCC No. 9616, is GRAS to the exclusion of the fermentation products of other safe, suitable, and harmless *P. f. subsp. shermanii* strains.

Specifically, Rhodia's substantiation of the GRAS claim is based predominately on the safety of the entire population of organisms that are classified as *P. f. subsp. shermanii*, as evidenced by the use in cheese production over the centuries and supported by Rhodia's ATCC No. 9616 strain-specific documentation. Further, Rhodia's independent expert panel found in its 2002 GRAS determination that *P. f. subsp. shermanii* is "a non-pathogenic, non-toxigenic organism that has a long history of safe use in food, and is, therefore, safe and suitable for use in food." without reference to a particular isolate of this organism. This approach is consistent with the use of other safe and suitable microorganisms in food such as *Lactococcus lactis* where all strains are considered safe and suitable for use in food so long as the isolates are confirmed to *L. lactis* by standard methodologies.

As isolate ATCC No. 9616 is one of many safe and suitable isolates of the *P. f. subsp. shermanii* group, Rhodia requests that you remove the isolate specific designation from the substance name in GRAS Notice 128 and consider Rhodia's notice to include skim milk or dextrose cultured with any safe and suitable *Propionibacterium freudenreichii subs. shermanii* strain.

It is asked that you incorporate this letter as an addendum to GRAS Notice 128 for the purpose of correcting and clarifying the comments/questions raised in your email to me. Should you have any other questions regarding GRAS Notice 128, please contact me so that Rhodia may promptly respond. Thank you.

Sincerely,

Robert H. Sindt

Cc: Kevin Gillies, Rhodia Inc.

RHS/bs